



US011638664B2

(12) **United States Patent**
Hunt et al.

(10) **Patent No.:** **US 11,638,664 B2**
(45) **Date of Patent:** **May 2, 2023**

(54) **BIOCOMPATIBLE ENCAPSULATION AND COMPONENT STRESS RELIEF FOR SENSOR ENABLED NEGATIVE PRESSURE WOUND THERAPY DRESSINGS**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 109 days.

(21) Appl. No.: **16/634,071**

(22) PCT Filed: **Jul. 23, 2018**

(86) PCT No.: **PCT/EP2018/069883**

§ 371 (c)(1),
(2) Date: **Jan. 24, 2020**

(87) PCT Pub. No.: **WO2019/020550**

PCT Pub. Date: **Jan. 31, 2019**

(65) **Prior Publication Data**

US 2020/0163802 A1 May 28, 2020

Related U.S. Application Data

(60) Provisional application No. 62/556,461, filed on Sep. 10, 2017, provisional application No. 62/536,921, (Continued)

(30) **Foreign Application Priority Data**

Mar. 21, 2018 (GB) 1804502

(51) **Int. Cl.**
A61F 13/00 (2006.01)
A61F 13/02 (2006.01)

(52) **U.S. Cl.**
CPC .. *A61F 13/00987* (2013.01); *A61F 13/00038* (2013.01); *A61F 13/00068* (2013.01); *A61F 13/0286* (2013.01); *A61F 2013/0094* (2013.01)

(58) **Field of Classification Search**
CPC A61F 13/00987; A61F 13/00038; A61F 13/00068; A61F 13/0286;
(Continued)

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Primary Examiner — Tatyana Zalukaeva

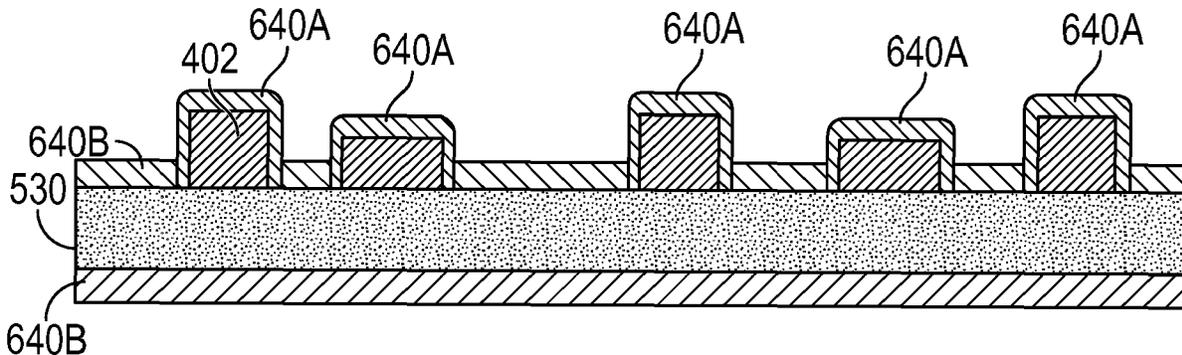
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(57) **ABSTRACT**

Devices and methods for encapsulating a portion of a wound dressing with biocompatible coating are disclosed. In some embodiments, a method includes coating a first side of a flexible wound contact layer of the wound dressing with a

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hydrophobic coating. The first side of the wound contact layer can support a plurality of electronic components. The method can further include coating a second side of the wound contact layer opposite the first side with the hydrophobic coating. The wound contact layer can be formed at least partially from hydrophilic material.

21 Claims, 26 Drawing Sheets

Related U.S. Application Data

filed on Jul. 25, 2017, provisional application No. 62/536,926, filed on Jul. 25, 2017.

(58) Field of Classification Search

CPC A61F 2013/0094; A61F 13/0216; A61F 13/00055; H01L 23/3135; H01L 23/3185; H01L 23/3121; H01L 23/3171; H01L 2924/181; H05K 2201/0116; H05K 2201/0145; H05K 2201/015; H05K 2201/10151; H05K 2201/10196; H05K 2203/1173; H05K 1/0283; H05K 1/189; H05K 3/284

See application file for complete search history.

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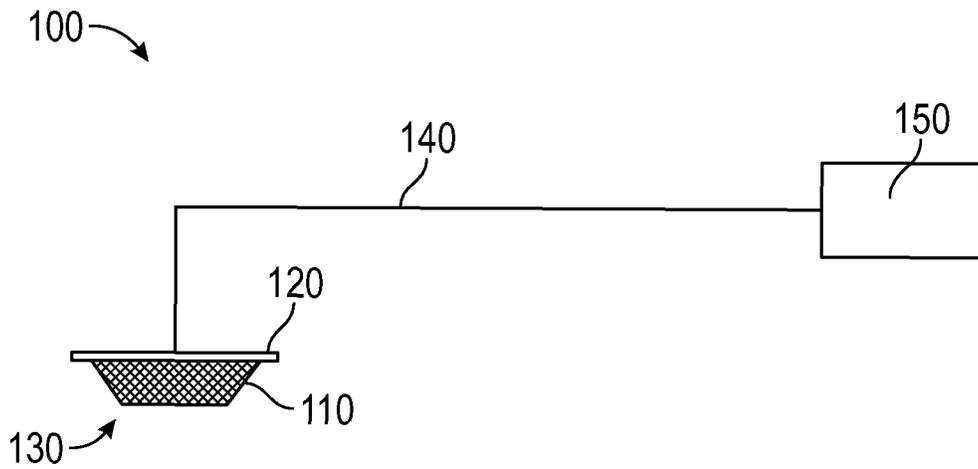


FIG. 1A

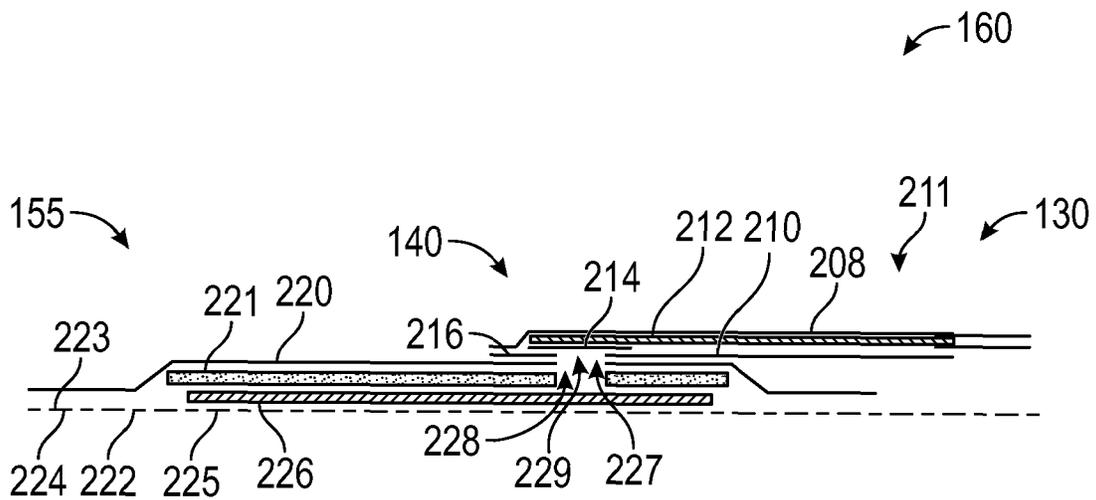


FIG. 1B

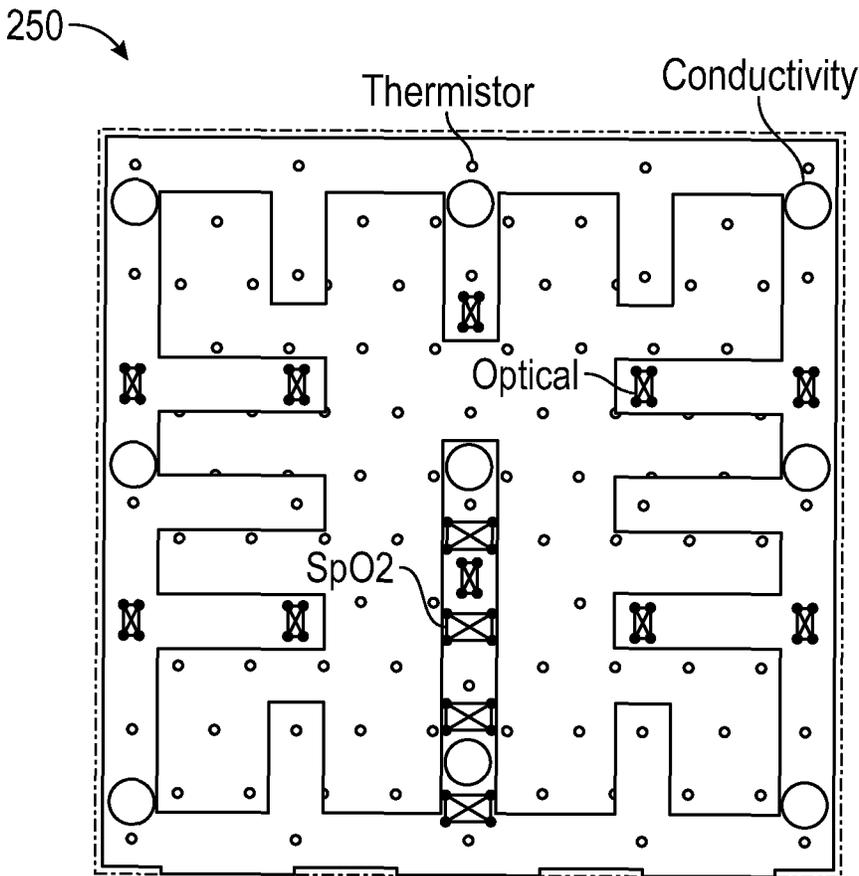


FIG. 2

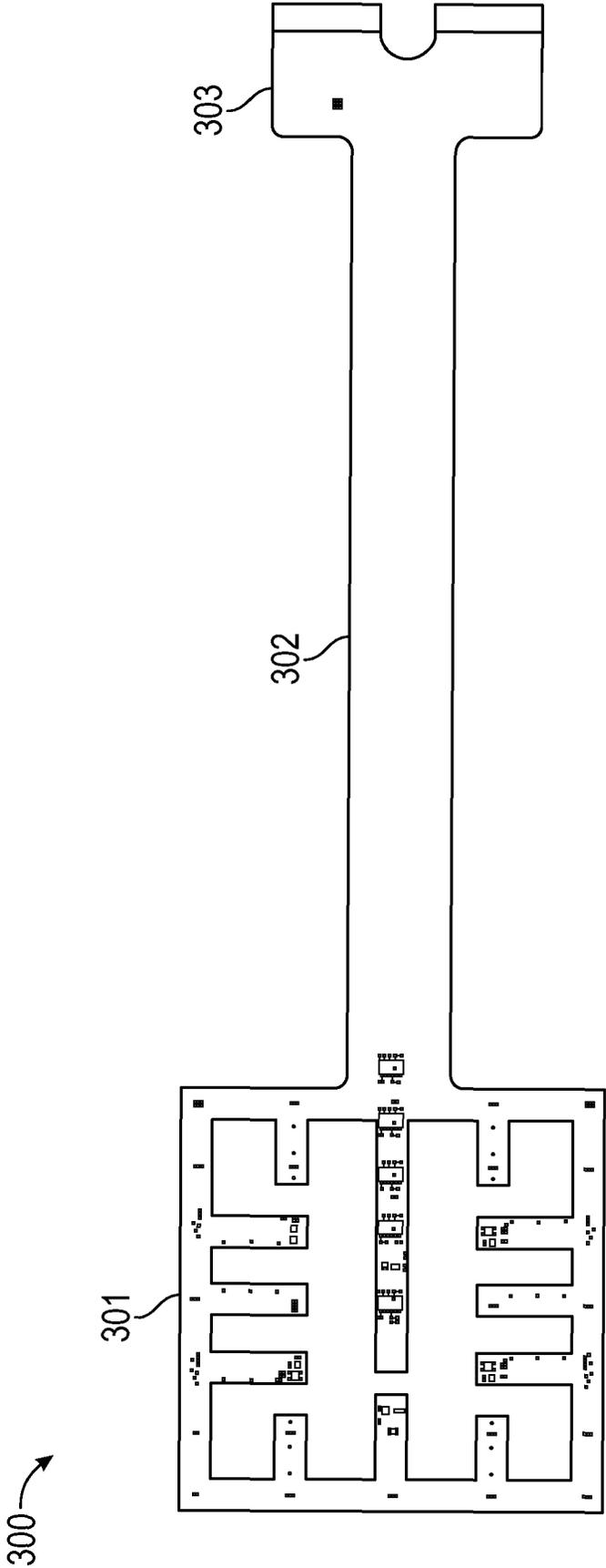


FIG. 3A

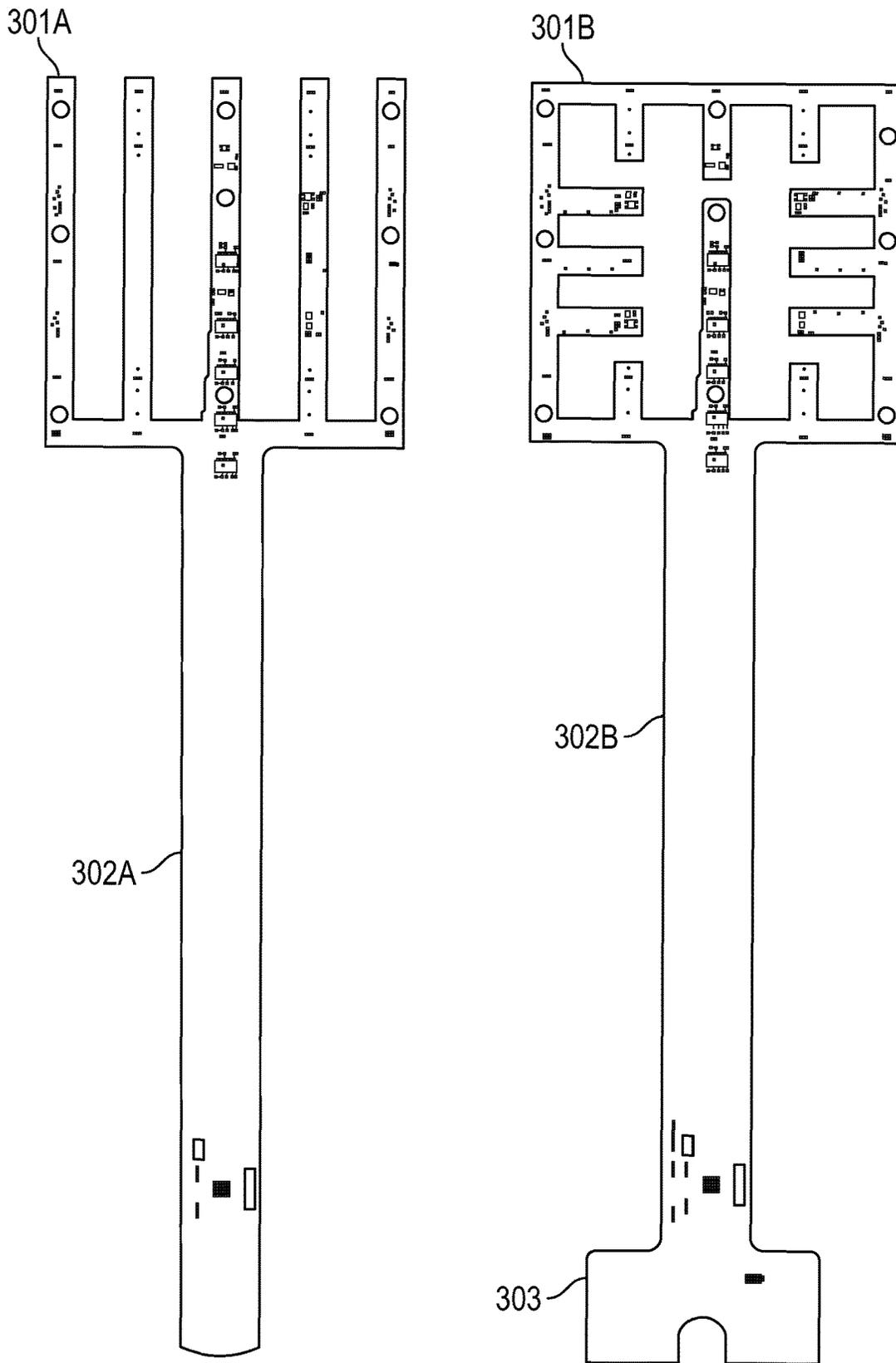


FIG. 3B

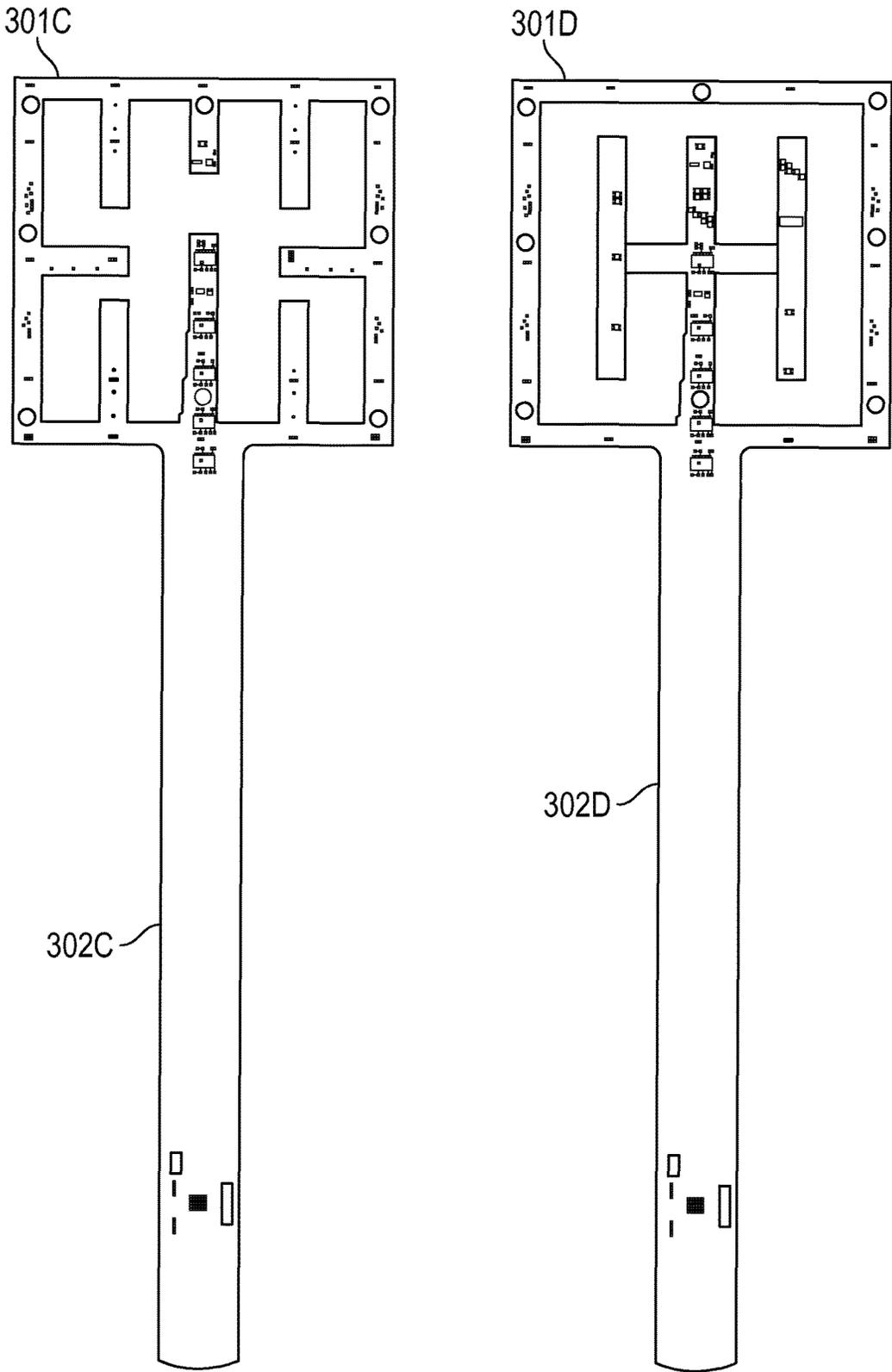


FIG. 3B
(Continued)

301B

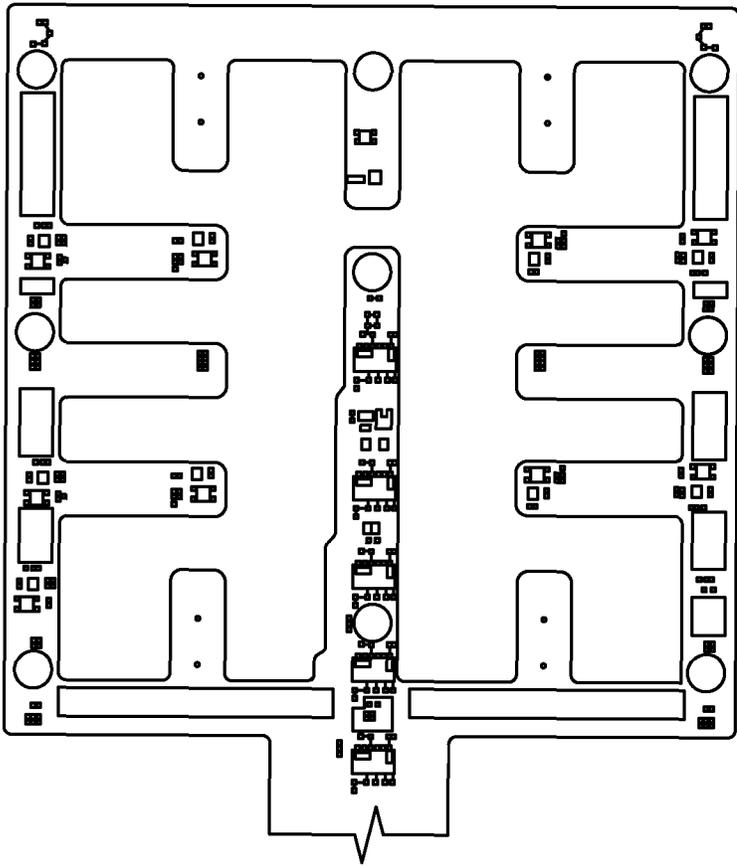


FIG. 3C

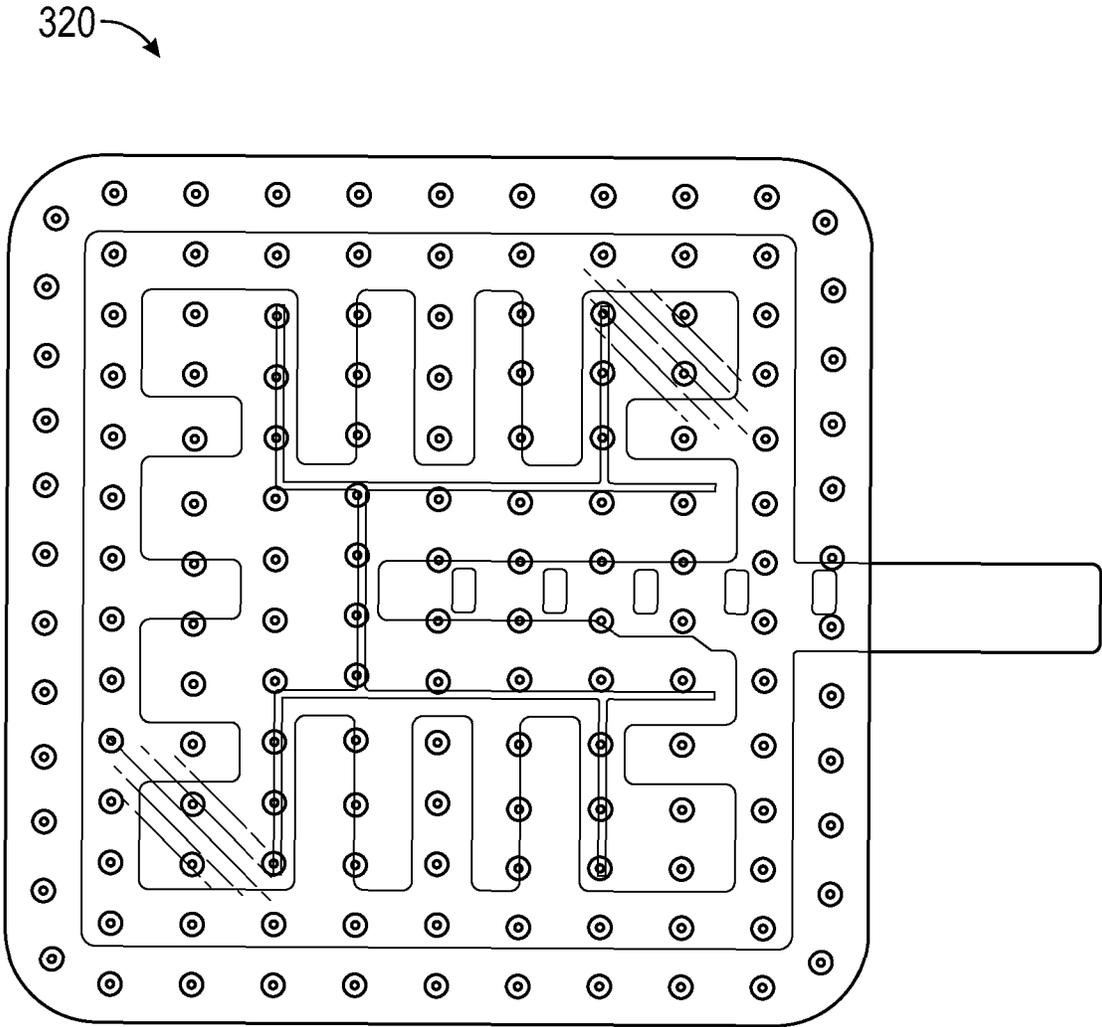


FIG. 3D

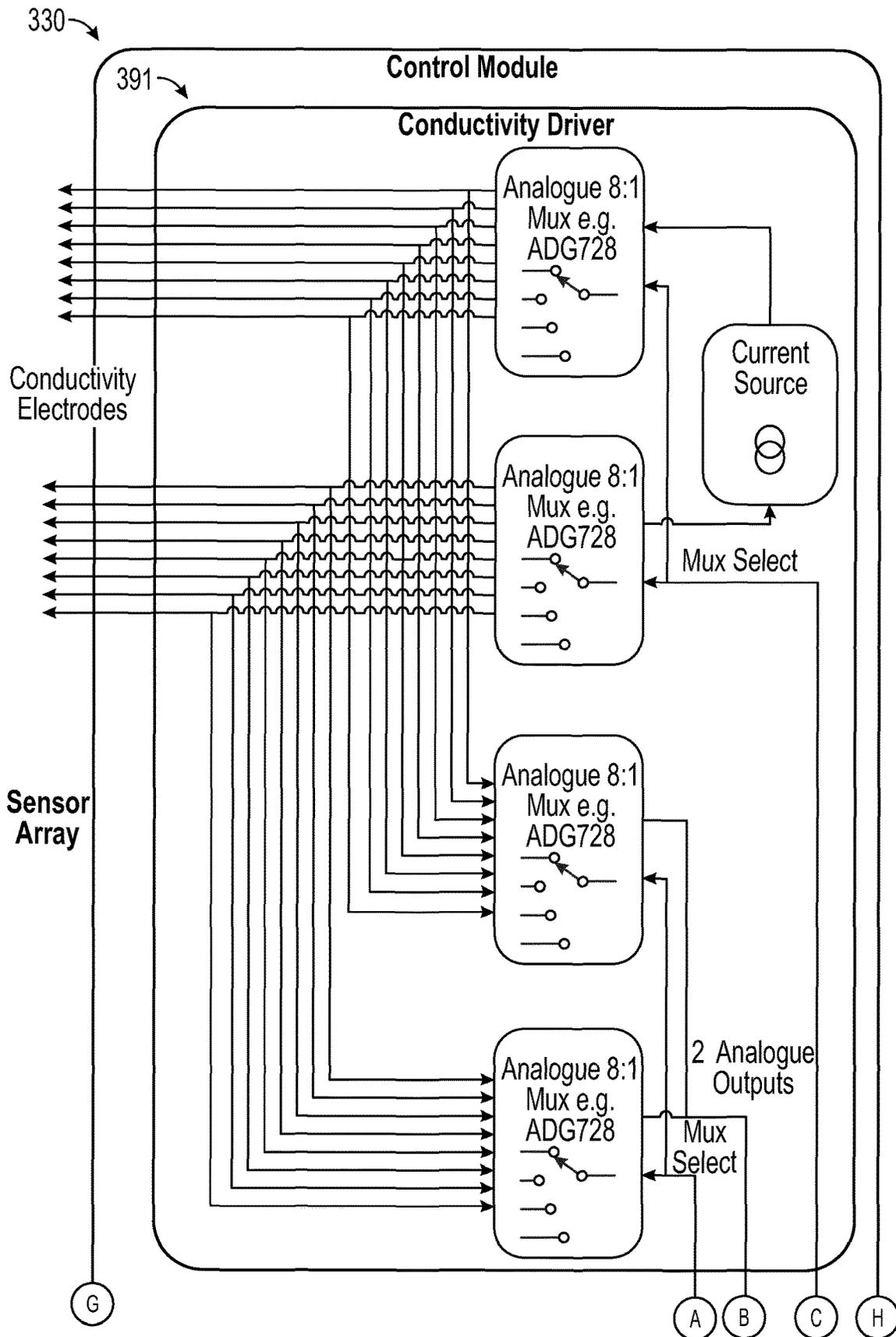


FIG. 3E

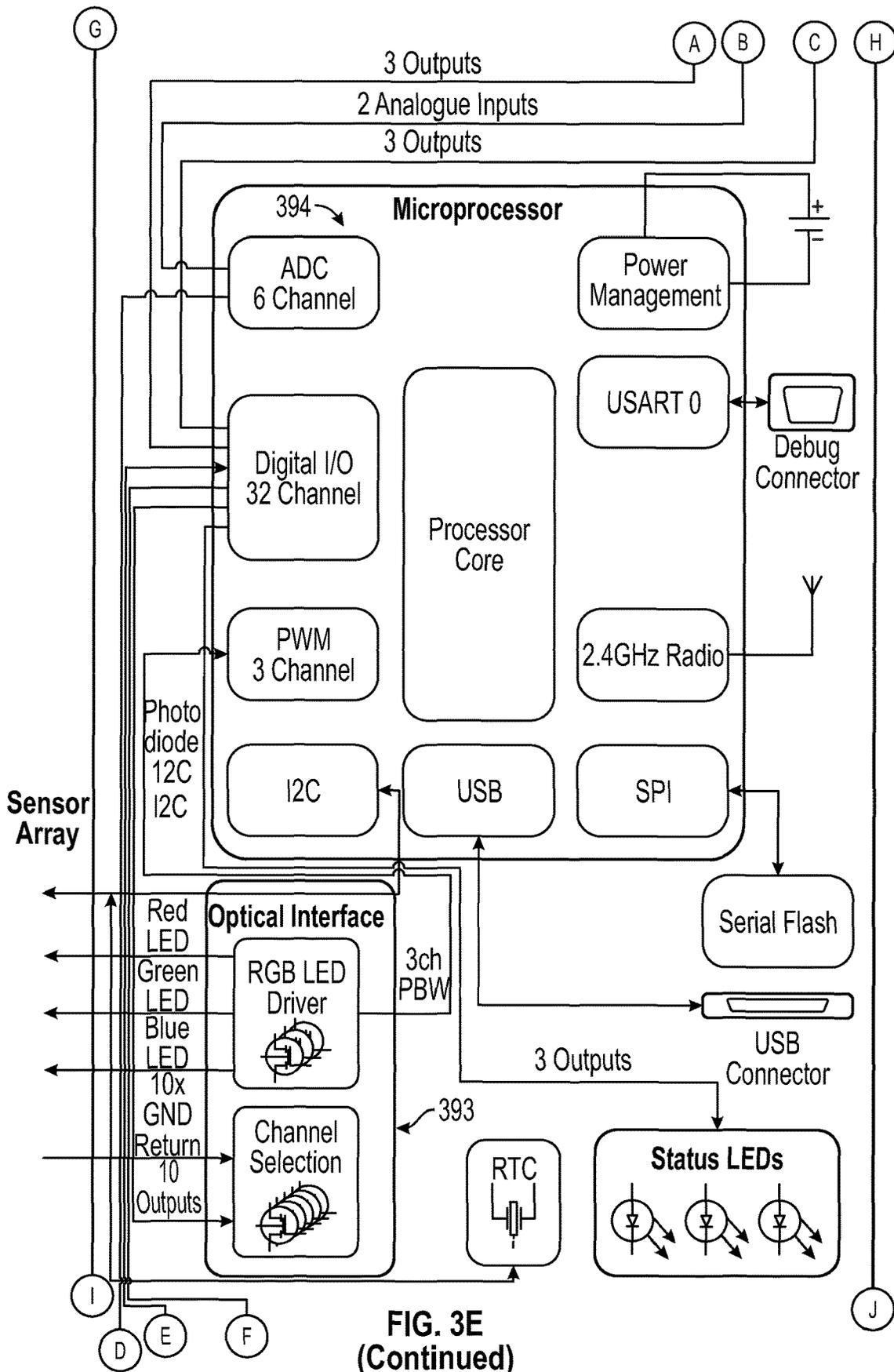


FIG. 3E
(Continued)

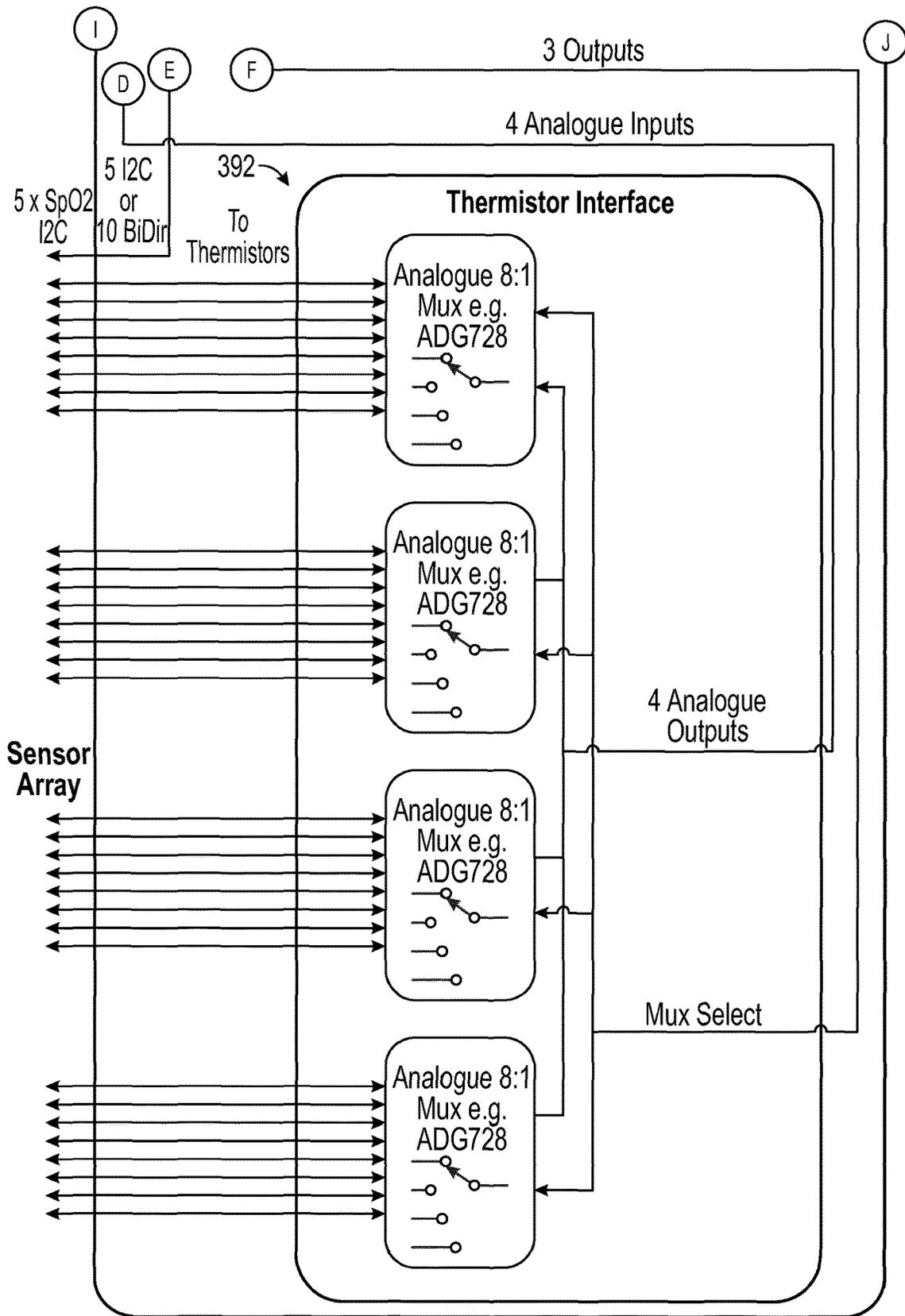


FIG. 3E
(Continued)

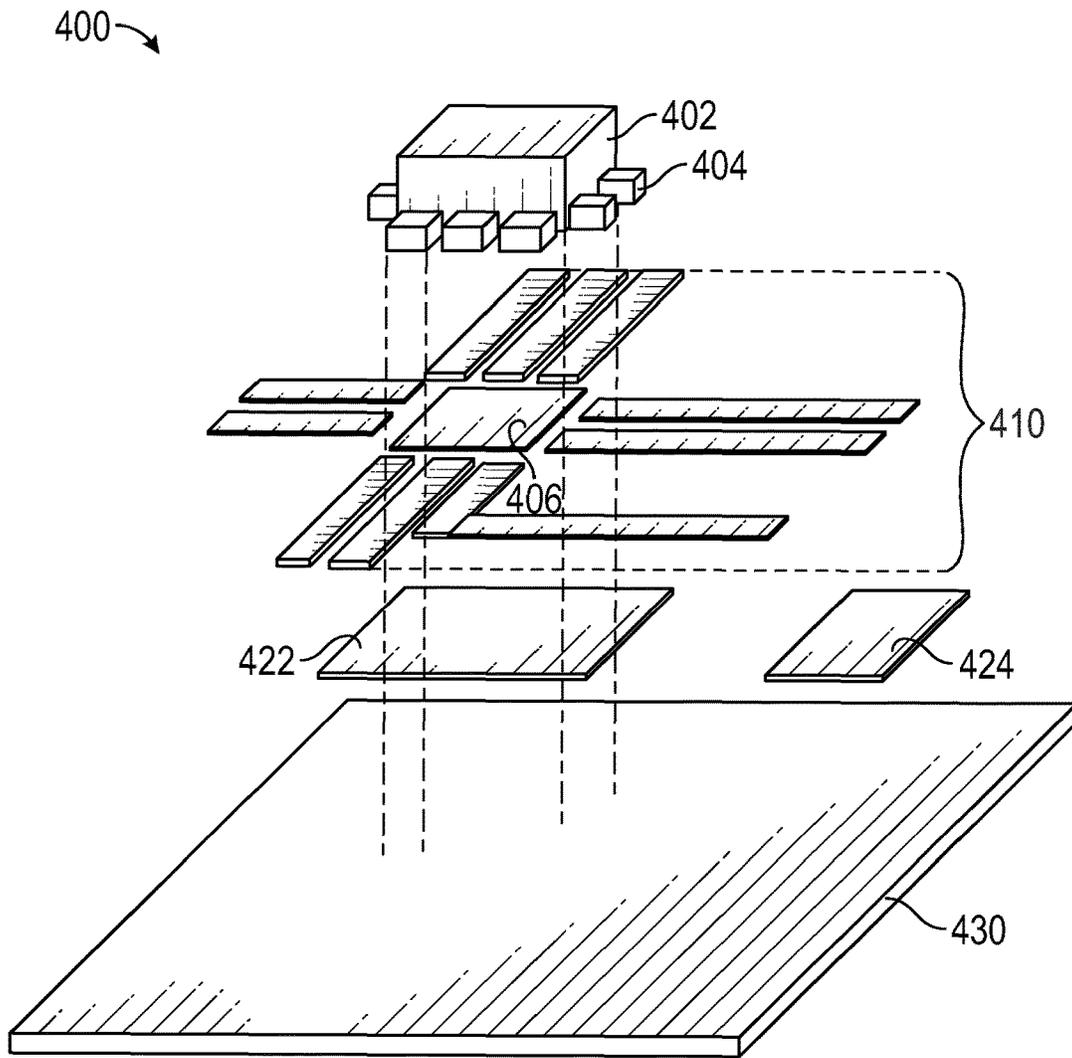


FIG. 4A

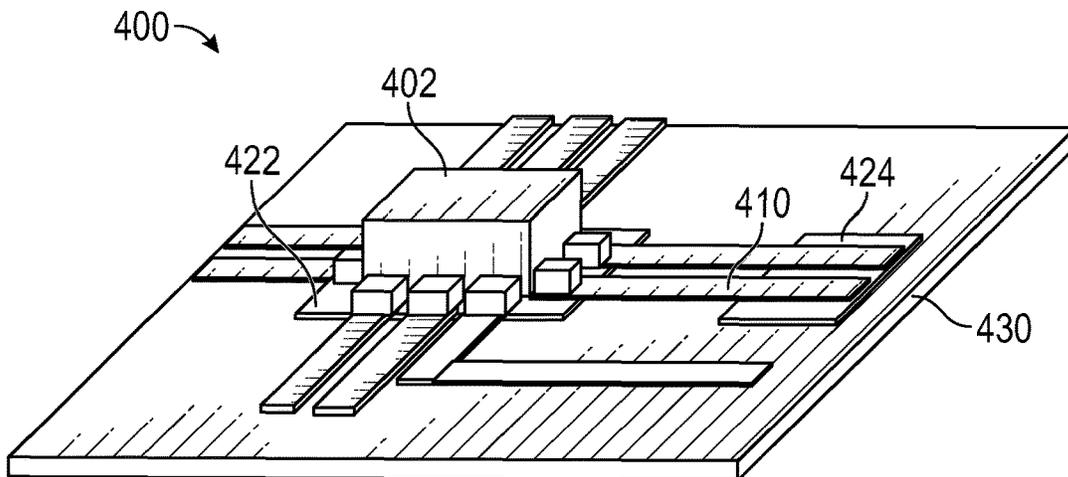


FIG. 4B

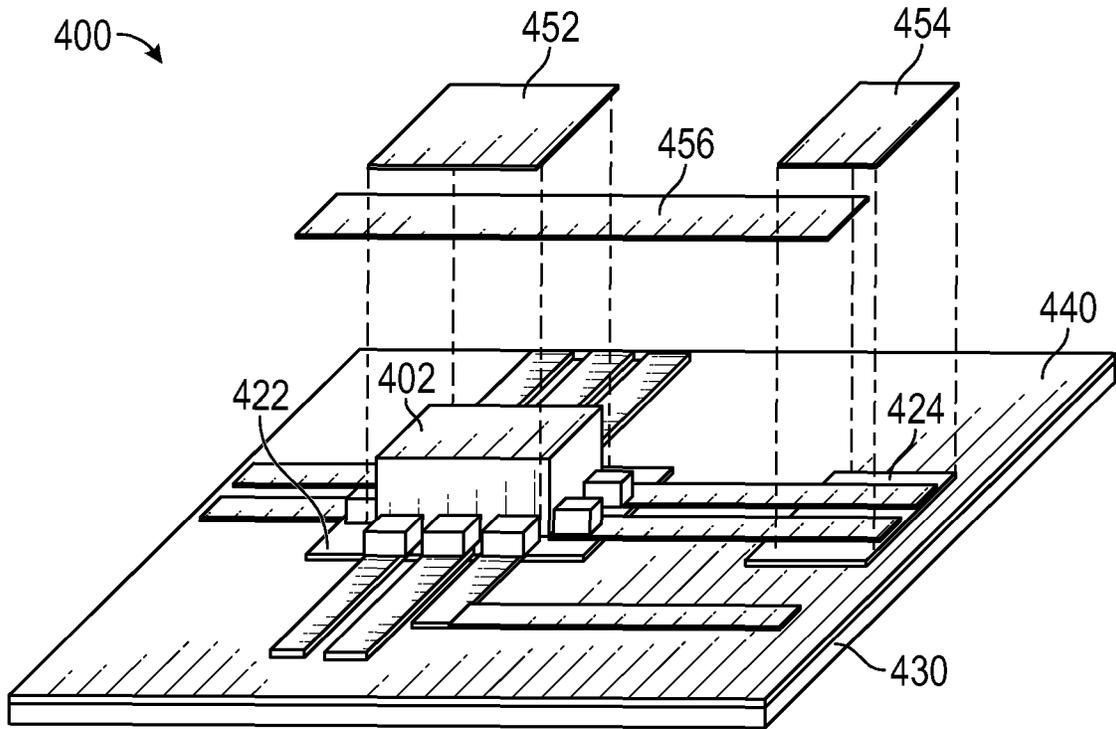


FIG. 4C

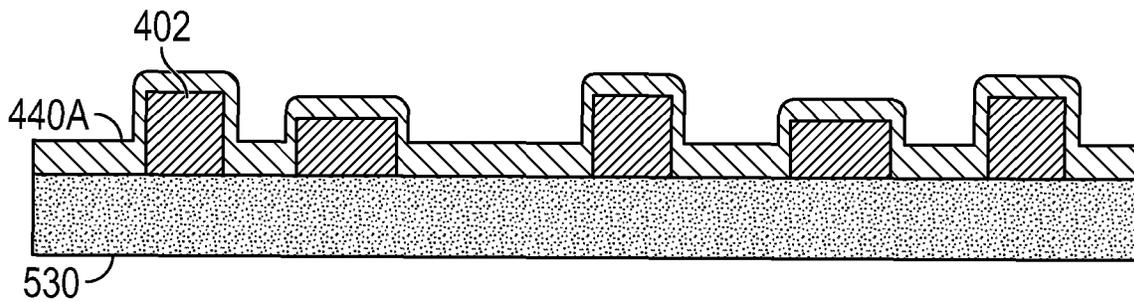


FIG. 5A

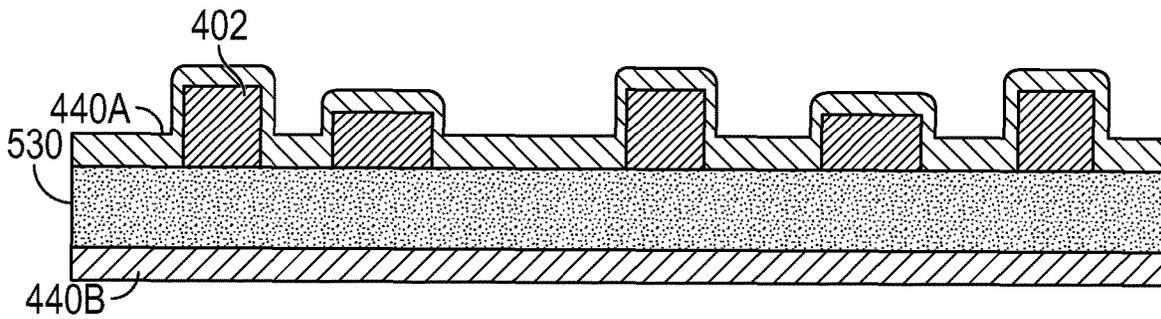


FIG. 5B

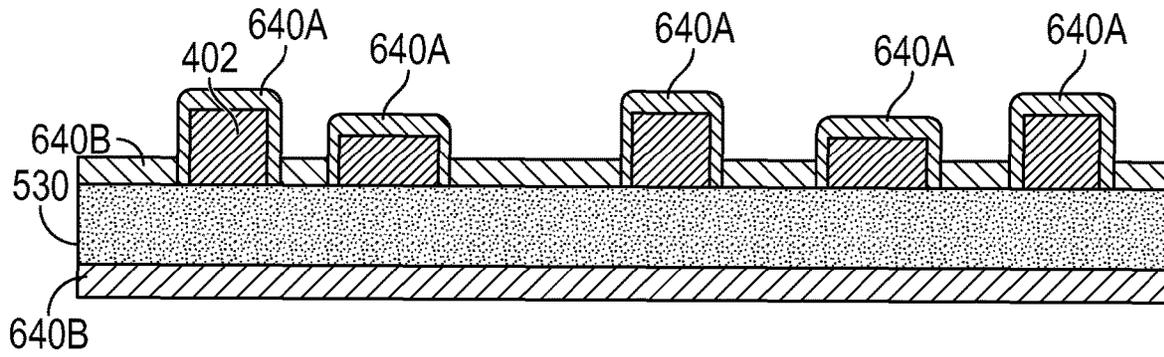


FIG. 6

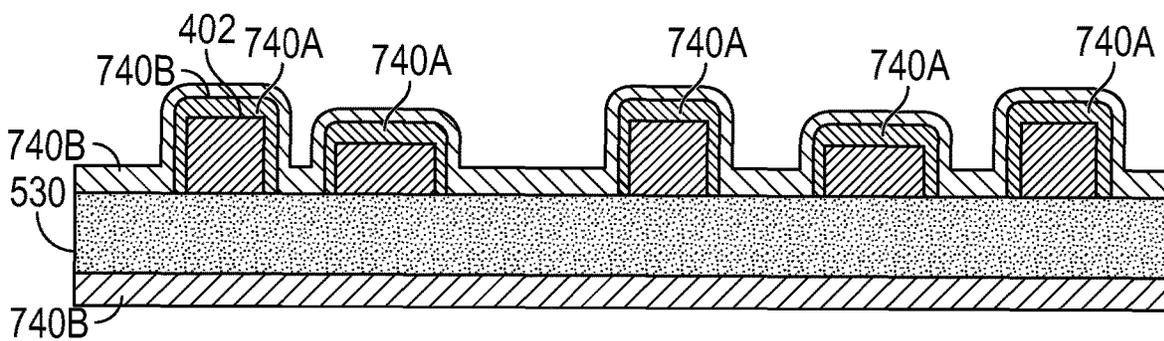


FIG. 7

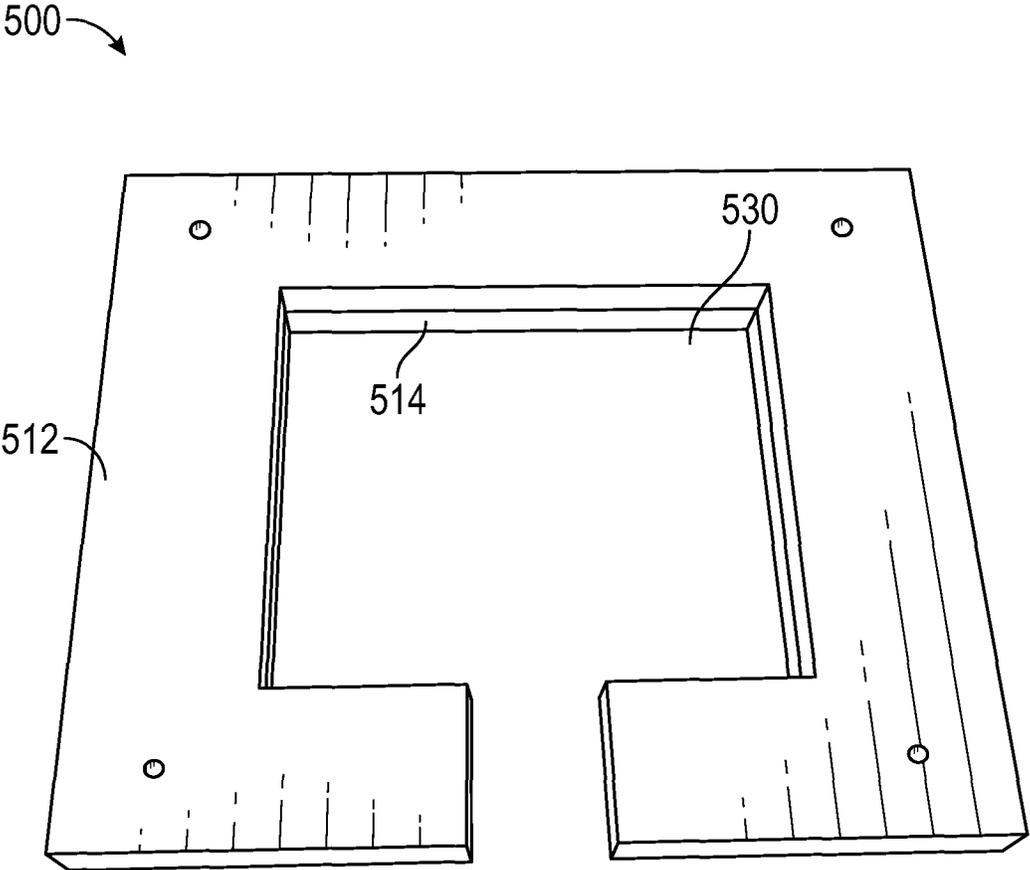


FIG. 8

600

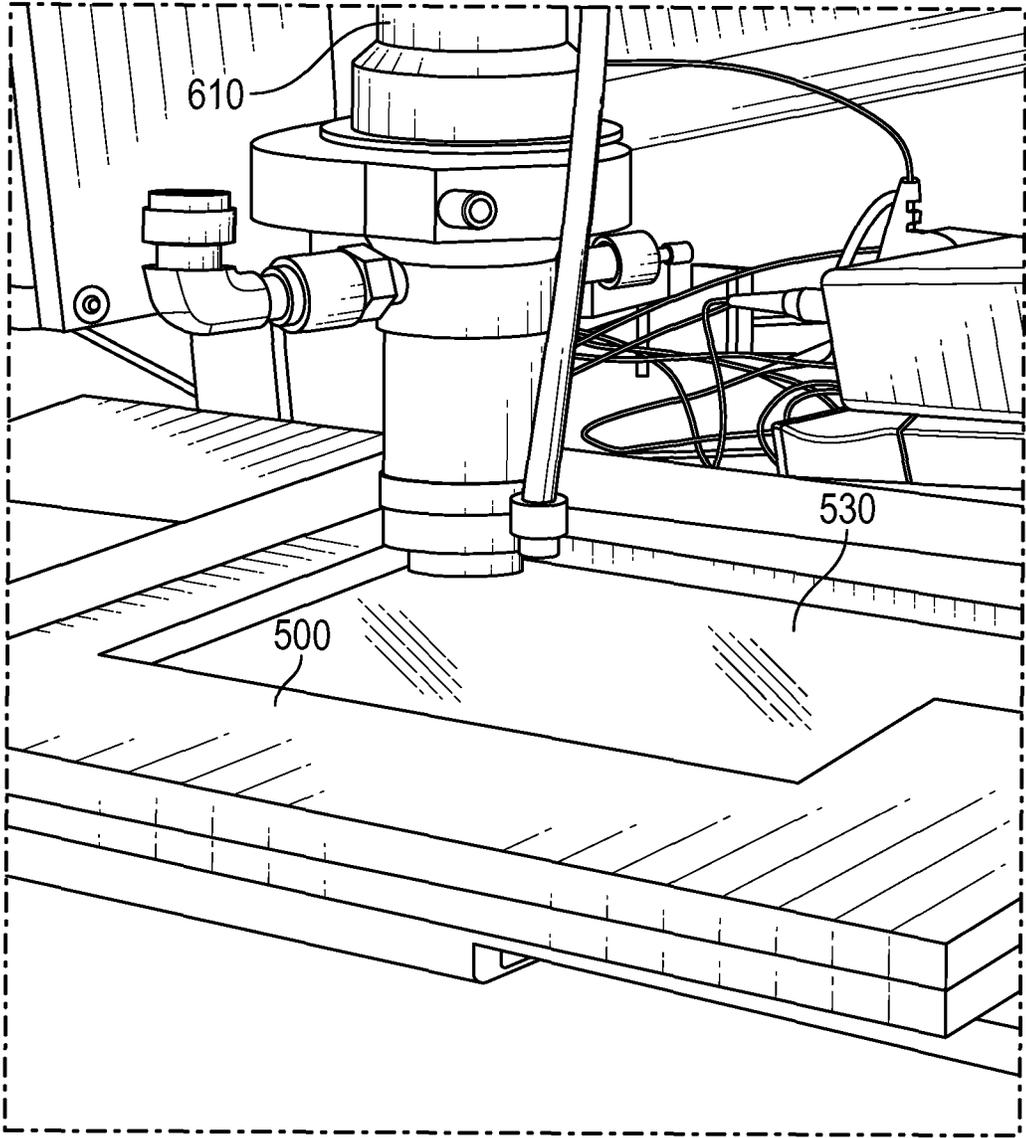


FIG. 9

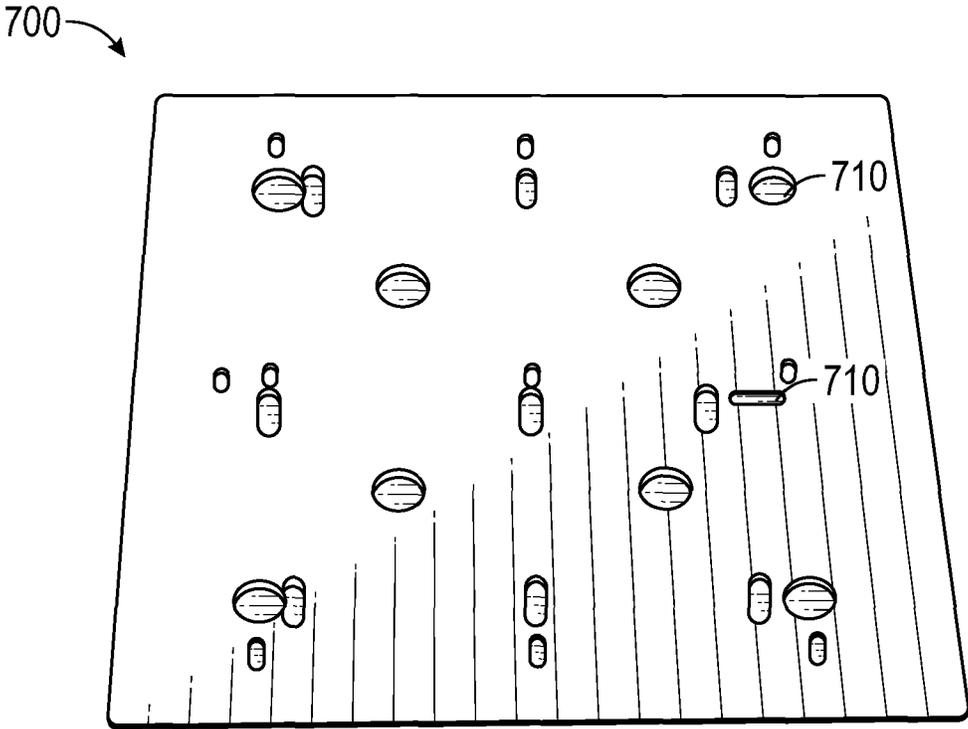


FIG. 10

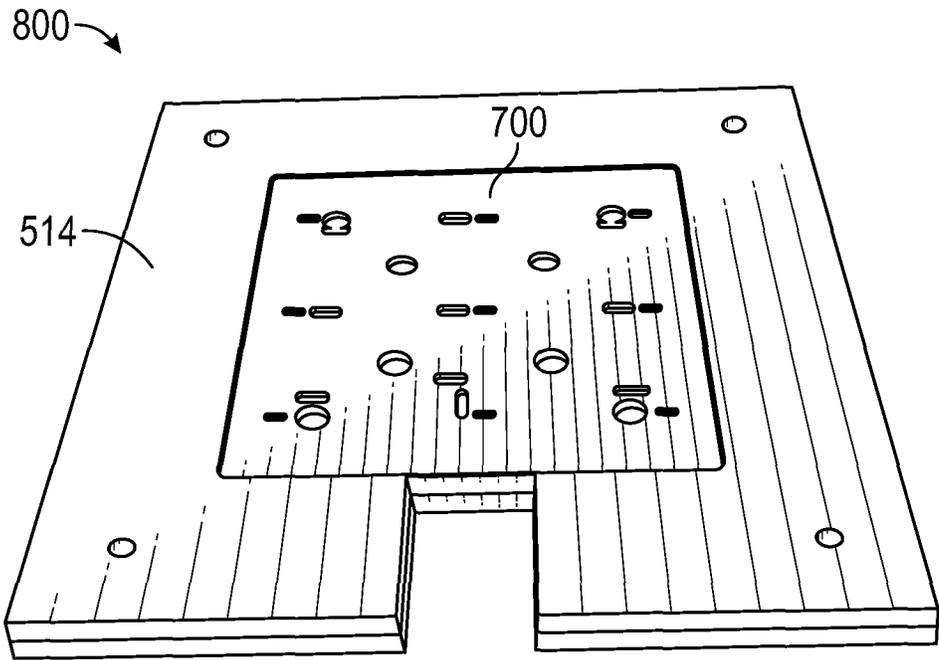


FIG. 11

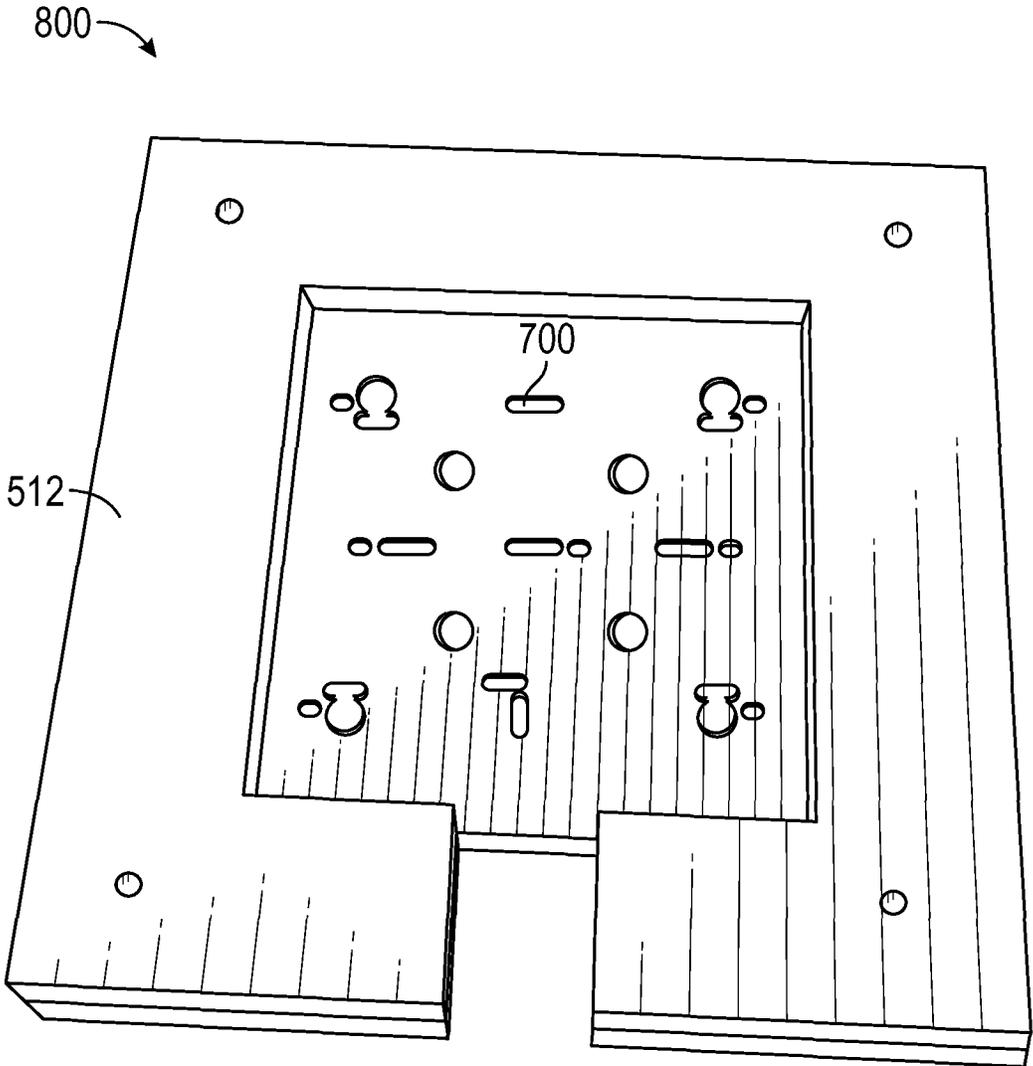


FIG. 12A

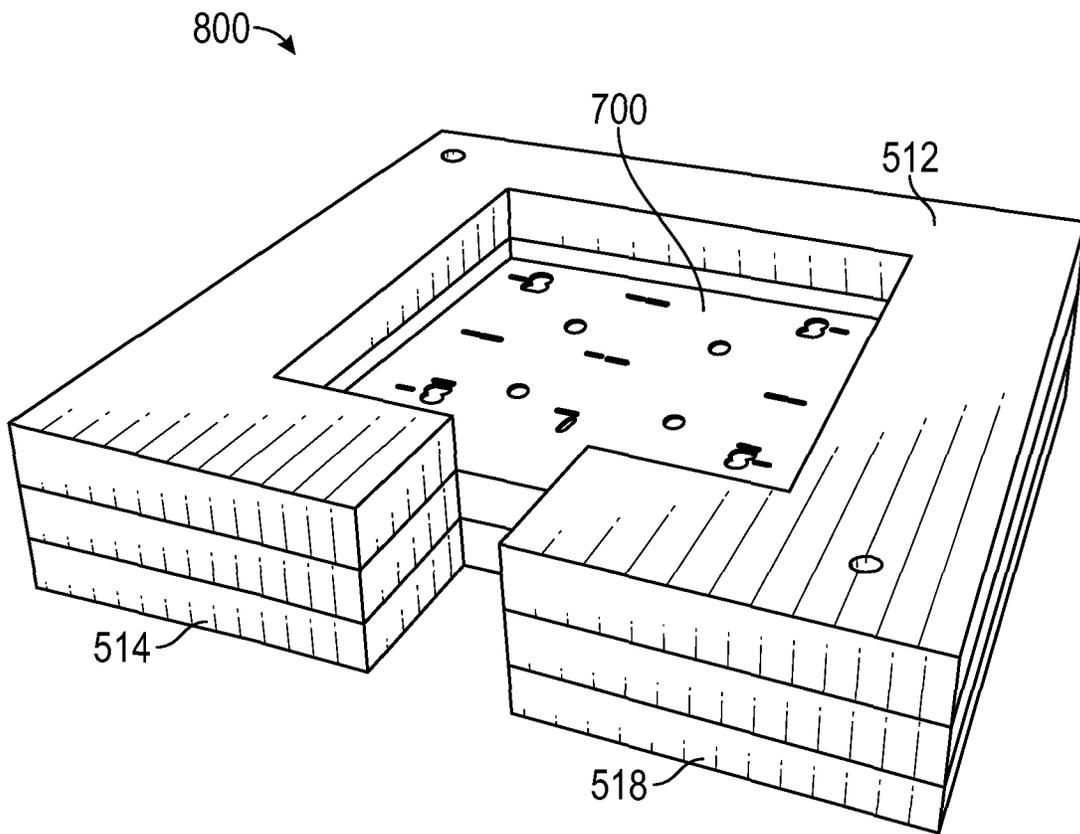


FIG. 12B

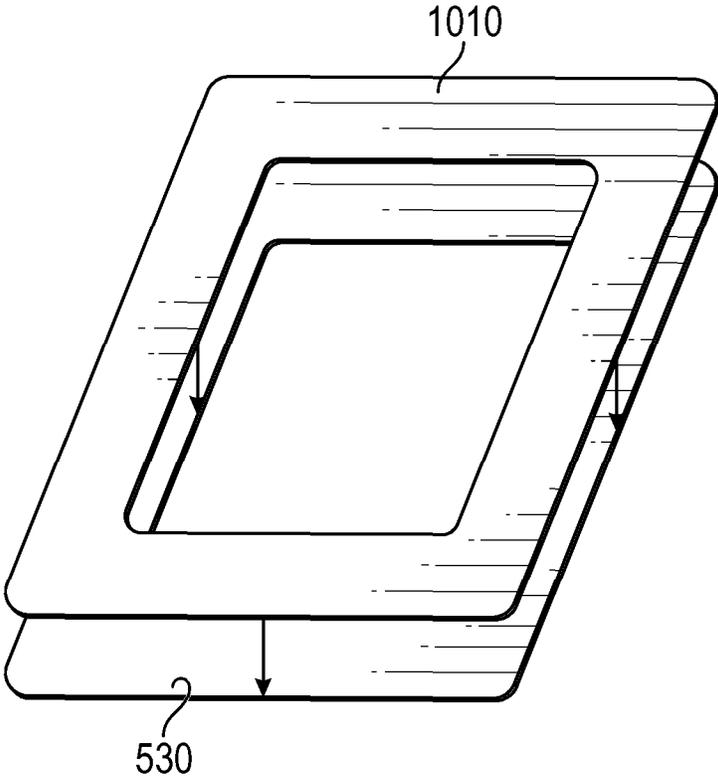


FIG. 13

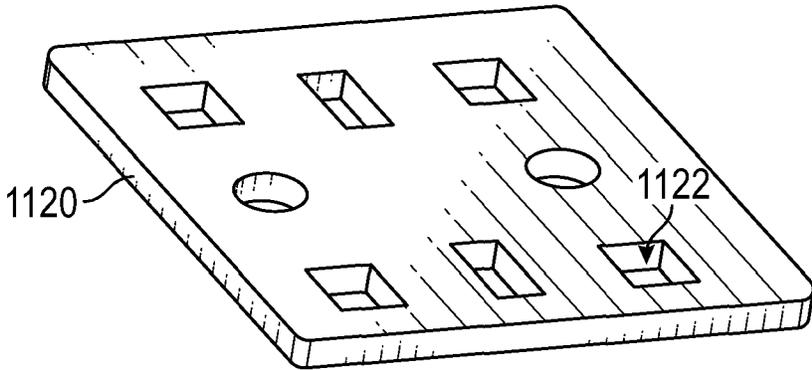
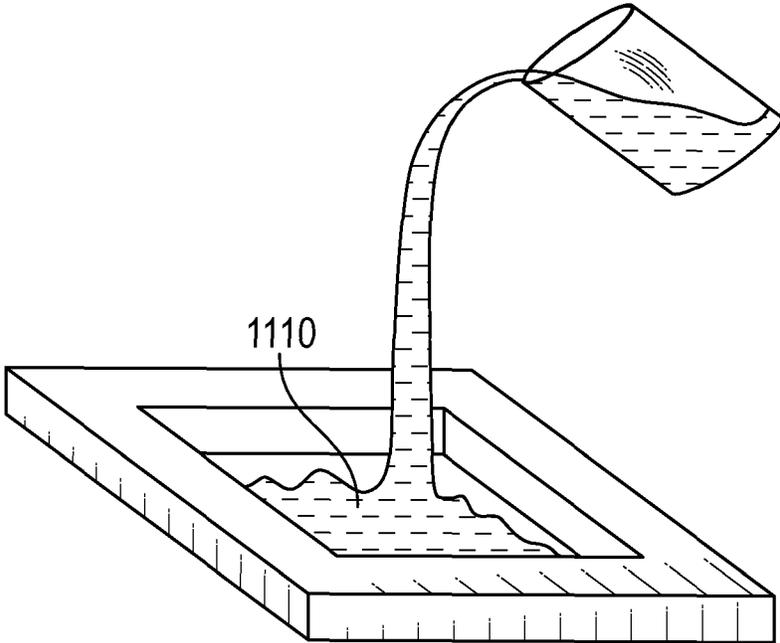


FIG. 14A

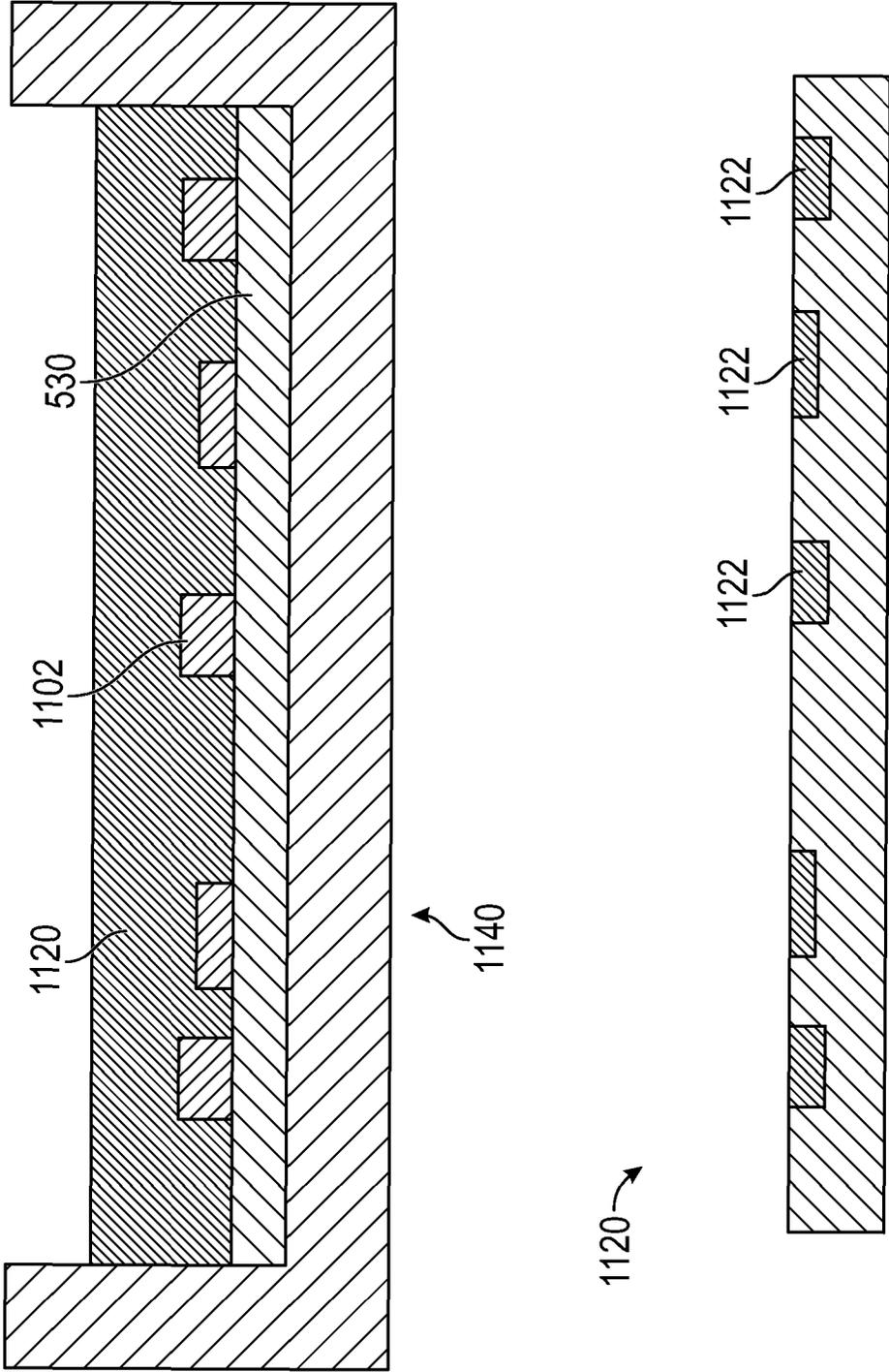


FIG. 14B

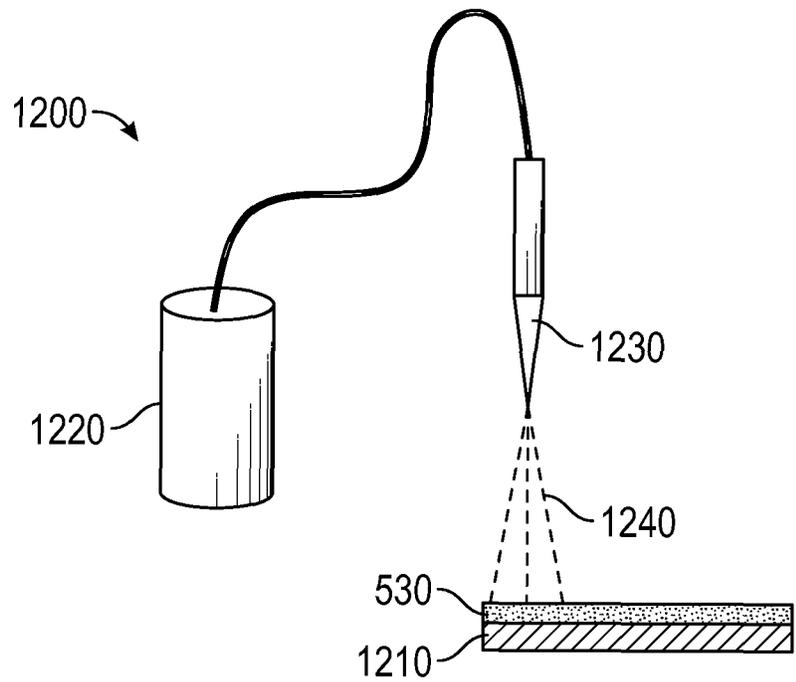


FIG. 15

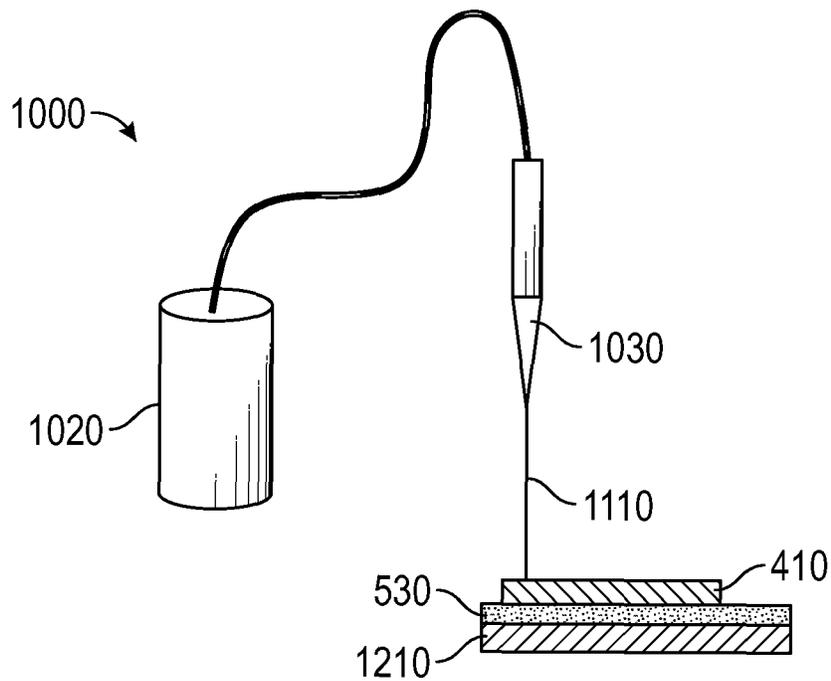


FIG. 16

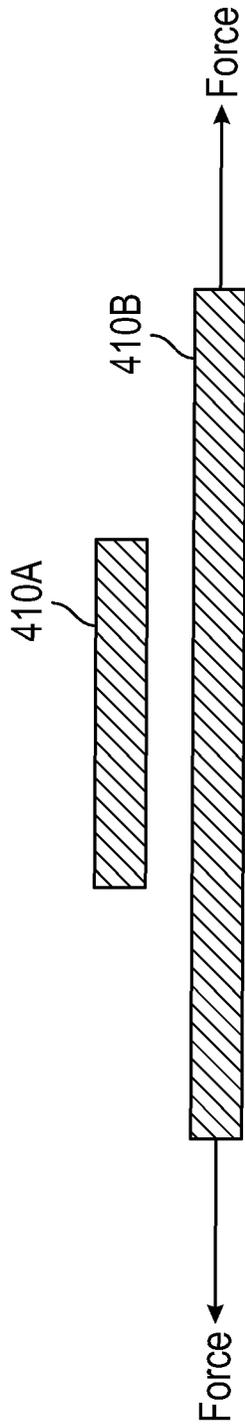


FIG. 17A

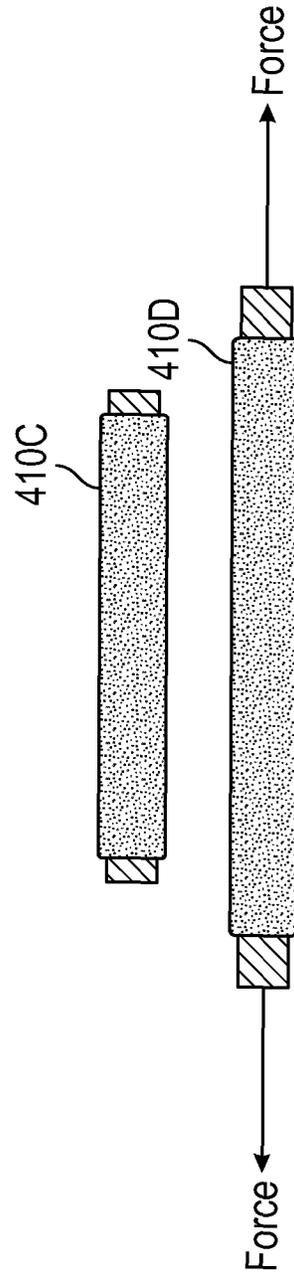


FIG. 17B

1800

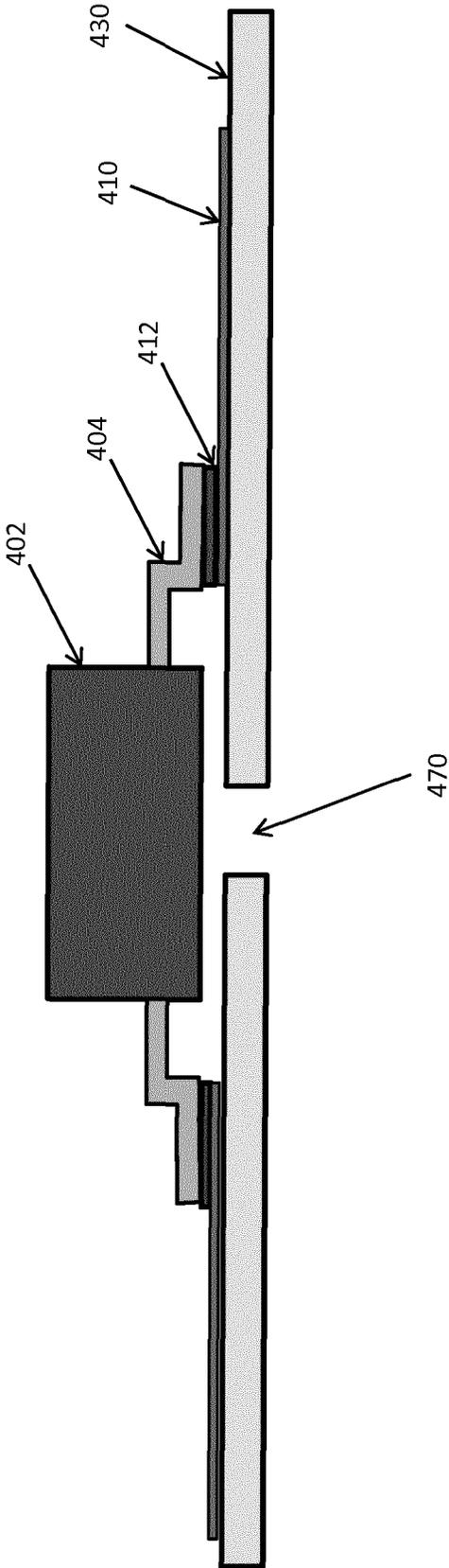


FIG. 18

1300A

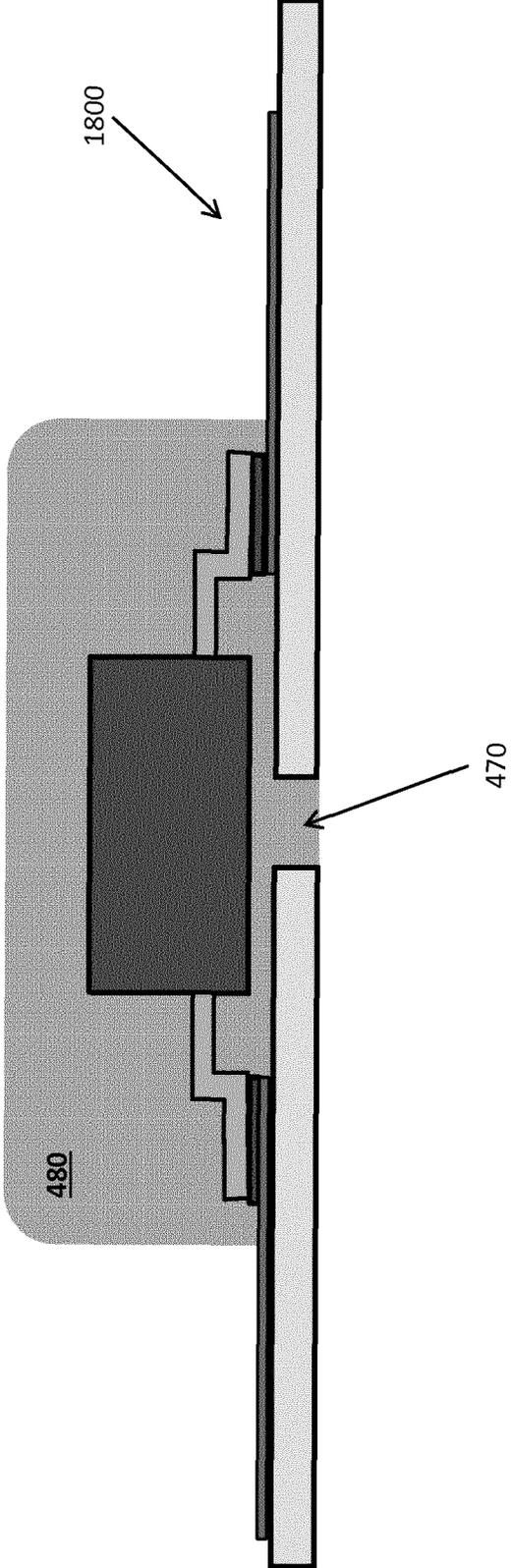


FIG. 19A

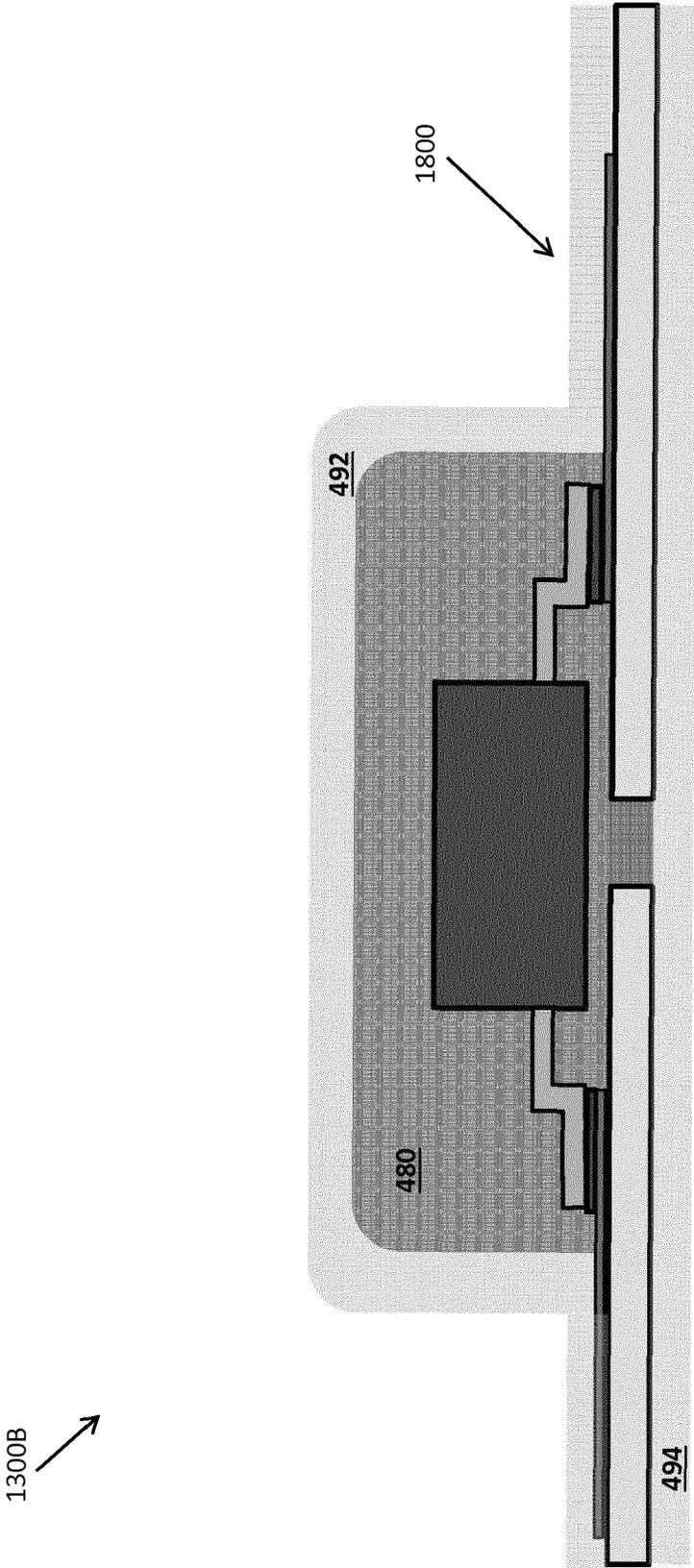


FIG. 19B

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**BIOCOMPATIBLE ENCAPSULATION AND
COMPONENT STRESS RELIEF FOR
SENSOR ENABLED NEGATIVE PRESSURE
WOUND THERAPY DRESSINGS**

RELATED APPLICATIONS

This application is a U.S. national stage application of International Patent Application No. PCT/EP2018/069883, filed Jul. 23, 2018, entitled "BIOCOMPATIBLE ENCAPSULATION AND COMPONENT STRESS RELIEF FOR SENSOR ENABLED NEGATIVE PRESSURE WOUND THERAPY DRESSINGS" which claims priority to U.S. Provisional Application No. 62/536,921, filed Jul. 25, 2017, entitled "BIOCOMPATIBLE ENCAPSULATION OF COMPONENTS IN SENSOR ENABLED NEGATIVE PRESSURE WOUND THERAPY DRESSINGS," U.S. Provisional Application No. 62/536,926, filed Jul. 25, 2017, entitled "BIOCOMPATIBLE ENCAPSULATION AND COMPONENT STRESS RELIEF FOR SENSOR ENABLED NEGATIVE PRESSURE WOUND THERAPY DRESSINGS," U.S. Provisional Application No. 62/556,461, filed Sep. 10, 2017, entitled "BIOCOMPATIBLE ENCAPSULATION AND COMPONENT STRESS RELIEF FOR SENSOR ENABLED NEGATIVE PRESSURE WOUND THERAPY DRESSINGS," and U.K. Provisional Application No. 1804502.1, filed Mar. 21, 2018, entitled "BIOCOMPATIBLE ENCAPSULATION AND COMPONENT STRESS RELIEF FOR SENSOR ENABLED NEGATIVE PRESSURE WOUND THERAPY DRESSINGS," the entireties of each of which are hereby incorporated by reference.

BACKGROUND

Field

Embodiments of the present disclosure relate to apparatuses, systems, and methods for the treatment of tissues via sensor-enabled monitoring in communication with various therapy regimes.

Description of the Related Art

Nearly all areas of medicine may benefit from improved information regarding the state of the tissue, organ, or system to be treated, particularly if such information is gathered in real-time during treatment, many types of treatments are still routinely performed without the use of sensor data collection. Instead, such treatments rely upon visual inspection by a caregiver or other limited means rather than quantitative sensor data. For example, in the case of wound treatment via dressings and/or negative pressure wound therapy, data collection is generally limited to visual inspection by a caregiver and often the underlying wounded tissue may be obscured by bandages or other visual impediments. Even intact, unwounded skin may have underlying damage that is not visible to the naked eye, such as a compromised vascular or deeper tissue damage that may lead to an ulcer. Similar to wound treatment, during orthopedic treatments requiring the immobilization of a limb with a cast or other encasement, only limited information is gathered on the underlying tissue. In instances of internal tissue repair, such as a bone plate, continued direct sensor-driven data collection is not performed. Further, braces and/or sleeves used to support musculoskeletal function do not monitor the functions of the underlying muscles or the movement of the

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limbs. Outside of direct treatments, common hospital room items such as beds and blankets could be improved by adding capability to monitor patient parameters.

Therefore, there is a need for improved sensor monitoring, particularly through the use of sensor-enabled substrates which can be incorporated into existing treatment regimes.

SUMMARY

According to some embodiments, there is provided a method for coating a wound dressing, the method comprising:

coating a first side of a flexible wound contact layer of the wound dressing with a hydrophobic coating, the first side of the wound contact layer supporting a plurality of electronic components; and

coating a second side of the wound contact layer opposite the first side with the hydrophobic coating, the wound contact layer formed at least partially from hydrophilic material.

The method for coating a wound dressing described in any of the preceding paragraphs may further comprise one or more of the following features. The method can include encapsulating the wound contact layer with the coating. The coating may be hydrophobic, biocompatible, and/or substantially stretchable. The plurality of electronic components may comprise at least one electronic connection. The method may further comprise coating at least some of the plurality of the electrical components with multiple layers of coating. Coating the first and second sides of the wound contact layer may comprise spraying the coating. Spraying comprises spraying with compressed air or inert gas. The coating may be formed from material compliant with IEC 60601 standard.

According to some embodiments, there is provided a method for coating a wound dressing, the method comprising:

coating a plurality of electronic components supported by a first side of a flexible wound contact layer of the wound dressing with a first biocompatible coating; and coating one or more remaining areas of the first side of the wound contact layer and a second side of the wound contact layer opposite the first side with a second biocompatible coating.

In some embodiments, described in any of the preceding paragraphs can include one or more of the following features. The first coating may be substantially non-stretchable. The first coating may comprise at least one of Dymax 20351, Dymax 20558, Dymax 9001-E, or Loctite 3211. The wound contact layer may be formed at least partially from hydrophilic material. The first and second coatings may be hydrophobic and/or formed from material compliant with IEC 60601 standard. The first coating can have viscosity of no more than about 50,000 centipoise.

According to some embodiments, there is provided a method for coating a wound dressing, the method comprising:

coating a plurality of electronic components supported by a first side of a flexible wound contact layer of the wound dressing with a non-biocompatible coating; and coating the first side of the wound contact layer including the plurality of electrical components and a second side of the wound contact layer opposite the first side with a biocompatible coating.

The method of any of the preceding paragraphs can include one or more of the following features. The non-biocompatible coating may be substantially non-stretchable.

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In some embodiments, Coating the first of the wound contact layer with the biocompatible coating comprises coating the non-biocompatible coating covering the plurality of electronic components. The biocompatible coating may be hydrophobic and/or formed from material compliant with IEC 60601 standard.

According to some embodiments, there is provided a method for coating a wound dressing, the method comprising:

- positioning substantially in tension between first and second frames a flexible wound contact layer of the wound dressing, the wound contact layer including a first side supporting a plurality of electronic components protruding from a surface of the first side and a second side opposite the first side, the second side being substantially smooth; and
- coating the wound contact layer with a biocompatible coating.

The method of any of the preceding paragraphs can include one or more of the following features. The method can further comprise supporting the first side of the wound contact layer in a substantially flat position by a mold, the mold including a plurality of recesses configured to support the plurality of electronic components; and substantially evenly applying the coating to the second side of the wound contact layer. The method may further comprise supporting between the first and second frames the second side of the wound contact layer in a substantially flat position; and substantially evenly applying the coating to the first side of the wound contact layer. In some embodiments, coating may comprise spraying the biocompatible coating and/or encapsulating the wound contact layer with the biocompatible coating. Spraying may comprise spraying with compressed air or inert gas. The biocompatible coating is formed from material compliant with IEC 60601 standard. In some embodiments, the method may further comprise making at least one perforation in the substantially flexible wound contact layer prior to coating the first side of the substantially flexible wound contact layer supporting the plurality of electronic components. The method may further comprise making the at least one perforation under at least one electronic component. The method may further comprise applying a higher pressure to the first side than to the second side of the substantially flexible wound contact layer when coating the first side.

According to some embodiments, there is provided a wound dressing prepared by a process comprising:

- placing a plurality of electronic components on a first side of a wound contact layer of the wound dressing, the wound contact layer formed at least partially from hydrophilic material;
- coating the first side of the wound contact layer including the plurality of electronic components with a hydrophobic coating; and
- coating a second side of the wound contact layer opposite the first side with the hydrophobic coating.

The wound dressing of any of the preceding paragraphs can include one or more of the following features. The wound contact layer may be flexible. The coating may be biocompatible, substantially stretchable and/or formed from material compliant with IEC 60601 standard. The process may further comprise, prior to coating the first side of the wound contact layer with the hydrophobic coating, coating the plurality of electronic components with another substantially non-stretchable coating. The process may further comprise making at least one perforation in the wound contact layer prior to coating the first side of the wound contact layer

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supporting the plurality of electronic components. The at least one perforation may be made under at least one electronic component. The process may further comprise applying a higher pressure to the first side than to the second side of the wound contact layer when coating the first side.

According to some embodiments, there is provided a wound dressing manufactured and/or coated by any of methods described herein.

According to some embodiments, there is provided a device for coating a wound dressing, the device comprising:

- a first frame;
- a second frame configured to be attached to the first frame and further configured to secure a flexible wound contact layer of the wound dressing between the first and second frames, the wound contact layer including a first side supporting a plurality of electronic components protruding from a surface of the first side and a second side opposite the first side, the second side being substantially smooth,
- wherein the first and second frames are configured to support the wound contact layer substantially in tension such that a biocompatible coating can be applied to the first and second sides of the wound contact layer.

The device of any of the preceding paragraphs can include one or more of the following features. The device may further comprise a base and a mold including a plurality of recesses configured to support the plurality of electronic components, the mold and the first frame configured to be positioned on the base, the mold further configured to support the first side of the wound contact layer in a substantially flat position to permit the coating to be substantially evenly applied to the second side of the wound contact layer. The mold may be configured to support a plurality of wound contact layers in the substantially flat position, at least a first wound contact layer of the plurality of wound contact layers comprising different arrangement of electronic components that a second wound contact layer of the plurality of wound contact layers. The wound contact layer may comprise thermoplastic polyurethane. The coating may comprise urethane acrylate and/or may be applied to encapsulate the wound contact layer. At least one of the plate or the mold may comprise nylon or polytetrafluoroethylene (PTFE). In some embodiments, the coating may be applied as a spray. The device may further comprise a spraying device including a reservoir filled with compressed air or inert gas and configured to dispense uncured coating onto the wound contact layer thereby causing removal of oxygen and allowing the coating to cure. The wound contact layer may be configured to be used for provision of negative pressure wound therapy.

According to some embodiments, there is provided a device for coating a wound dressing, the device comprising:

- a body including a plurality of recesses configured to support the plurality of electronic components supported on a first side of a wound contact layer of the wound dressing, the plurality of electronic components protruding from a surface of the first side, the wound contact layer further including a second substantially smooth side opposite the first side,
- wherein the body is configured to support the first side of the wound contact layer substantially in a flat position such that a biocompatible coating can be applied to the second side of the wound contact layer.

The device of any of the preceding paragraphs can include one or more of the following features. The plurality of

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recesses may be shaped and positioned and shaped to substantially match shape and positioning of the plurality of electronic components.

According to some embodiments, there is provided a method for coating an electronic device, the method comprising:

coating a first side of a flexible substrate of the electronic device with a hydrophobic coating, the first side of the substrate supporting a plurality of electronic components; and

coating a second side of the substrate opposite the first side with the hydrophobic coating, the substrate formed at least partially from hydrophilic material.

According to some embodiments, there is provided a method for coating an electronic device, the method comprising:

coating a plurality of electronic components supported by a first side of a flexible substrate of the electronic device with a first biocompatible coating; and

coating one or more remaining areas of the first side of the substrate and a second side of the substrate opposite the first side with a second biocompatible coating.

According to some embodiments, there is provided a method for coating an electronic device, the method comprising:

coating a plurality of electronic components supported by a first side of a flexible substrate of the electronic device with a non-biocompatible coating; and

coating the first side of the substrate including the plurality of electrical components and a second side of the substrate opposite the first side with a biocompatible coating.

According to some embodiments, there is provided a method for coating an electronic device, the method comprising:

positioning substantially in tension between first and second frames a flexible substrate of the electronic device, the substrate including a first side supporting a plurality of electronic components protruding from a surface of the first side and a second side opposite the first side, the second side being substantially smooth; and

coating the substrate with a biocompatible coating.

Other embodiments of a wound dressing, devices, kits and associated methods are described below.

BRIEF DESCRIPTION OF THE DRAWINGS

Embodiments of the present disclosure will now be described hereinafter, by way of example only, with reference to the accompanying drawings in which:

FIG. 1A illustrates a negative pressure wound treatment system according to some embodiments;

FIG. 1B illustrates a wound dressing according to some embodiments;

FIG. 2 illustrates a sensor array illustrating the sensor placement incorporated into a wound dressing according to some embodiments;

FIG. 3A illustrates a flexible sensor array including a sensor array portion, a tail portion and a connector pad end portion according to some embodiments;

FIG. 3B illustrates flexible circuit boards with different sensor array geometries according to some embodiments;

FIG. 3C illustrates the sensor array portion of a sensor array shown in FIG. 3B;

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FIG. 3D illustrates a flexible sensor array incorporated into a perforated wound contact layer according to some embodiments;

FIG. 3E illustrates a control module according to some embodiments;

FIGS. 4A-4C illustrate a wound dressing with a plurality of electronic components according to some embodiments;

FIGS. 5A-5B illustrate coating(s) of a wound dressing according to some embodiments;

FIG. 6 illustrates coating a wound dressing with two biocompatible coatings according to some embodiments;

FIG. 7 illustrates coating a wound dressing with a biocompatible coating according to some embodiments;

FIG. 8 illustrates a device for coating a wound dressing according to some embodiments;

FIG. 9 illustrates spray coating a wound dressing according to some embodiments;

FIG. 10 illustrates a mold for coating a wound dressing according to some embodiments;

FIG. 11 illustrates another device for coating a wound dressing according to some embodiments;

FIGS. 12A-12B illustrate an assembled device for coating a wound dressing according to some embodiments;

FIG. 13 illustrates release liner for coating a wound dressing according to some embodiments;

FIGS. 14A-14B illustrate coating a wound dressing according to some embodiments;

FIG. 15 illustrates spray coating a wound dressing according to some embodiments;

FIG. 16 illustrates applying non-stretchable material to a wound dressing according to some embodiments;

FIGS. 17A-17B illustrate comparisons of performance without and with non-stretchable material according to some embodiments;

FIG. 18 illustrates a wound dressing with one or more perforations according to some embodiments; and

FIGS. 19A-B illustrate coating a wound dressing with one or more perforations according to some embodiments.

DETAILED DESCRIPTION

Embodiments disclosed herein relate to apparatuses and methods of monitoring and treating biological tissue with sensor-enabled substrates. The embodiments disclosed herein are not limited to treatment or monitoring of a particular type of tissue or injury, instead the sensor-enabled technologies disclosed herein are broadly applicable to any type of therapy that may benefit from sensor-enabled substrates. Some implementations utilize sensors and data collection relied upon by health care providers to make both diagnostic and patient management decisions.

Some embodiments disclosed herein relate to the use of sensors mounted on or embedded within substrates configured to be used in the treatment of both intact and damaged human or animal tissue. Such sensors may collect information about the surrounding tissue and transmit such information to a computing device or a caregiver to be utilized in further treatment. In certain embodiments, such sensors may be attached to the skin anywhere on the body, including areas for monitoring arthritis, temperature, or other areas that may be prone to problems and require monitoring. Sensors disclosed herein may also incorporate markers, such as radiopaque markers, to indicate the presence of the device, for example prior to performing an MRI or other technique.

The sensor embodiments disclosed herein may be used in combination with clothing. Non-limiting examples of cloth-

ing for use with embodiments of the sensors disclosed herein include shirts, pants, trousers, dresses, undergarments, outer-garments, gloves, shoes, hats, and other suitable garments. In certain embodiments, the sensor embodiments disclosed herein may be welded into or laminated into/onto the particular garments. The sensor embodiments may be printed directly onto the garment and/or embedded into the fabric. Breathable and printable materials such as microporous membranes may also be suitable.

Sensor embodiments disclosed herein may be incorporated into cushioning or bed padding, such as within a hospital bed, to monitor patient characteristics, such as any characteristic disclosed herein. In certain embodiments, a disposable film containing such sensors could be placed over the hospital bedding and removed/replaced as needed.

In some implementations, the sensor embodiments disclosed herein may incorporate energy harvesting, such that the sensor embodiments are self-sustaining. For example, energy may be harvested from thermal energy sources, kinetic energy sources, chemical gradients, or any suitable energy source.

The sensor embodiments disclosed herein may be utilized in rehabilitation devices and treatments, including sports medicine. For example, the sensor embodiments disclosed herein may be used in braces, sleeves, wraps, supports, and other suitable items. Similarly, the sensor embodiments disclosed herein may be incorporated into sporting equipment, such as helmets, sleeves, and/or pads. For example, such sensor embodiments may be incorporated into a protective helmet to monitor characteristics such as acceleration, which may be useful in concussion diagnosis.

The sensor embodiments disclosed herein may be used in coordination with surgical devices, for example, the NAVIO surgical system by Smith & Nephew Inc. In implementations, the sensor embodiments disclosed herein may be in communication with such surgical devices to guide placement of the surgical devices. In some implementations, the sensor embodiments disclosed herein may monitor blood flow to or away from the potential surgical site or ensure that there is no blood flow to a surgical site. Further surgical data may be collected to aid in the prevention of scarring and monitor areas away from the impacted area.

To further aid in surgical techniques, the sensors disclosed herein may be incorporated into a surgical drape to provide information regarding tissue under the drape that may not be immediately visible to the naked eye. For example, a sensor embedded flexible drape may have sensors positioned advantageously to provide improved area-focused data collection. In certain implementations, the sensor embodiments disclosed herein may be incorporated into the border or interior of a drape to create fencing to limit/control the surgical theater.

Sensor embodiments as disclosed herein may also be utilized for pre-surgical assessment. For example, such sensor embodiments may be used to collect information about a potential surgical site, such as by monitoring skin and the underlying tissues for a possible incision site. For example, perfusion levels or other suitable characteristics may be monitored at the surface of the skin and deeper in the tissue to assess whether an individual patient may be at risk for surgical complications. Sensor embodiments such as those disclosed herein may be used to evaluate the presence of microbial infection and provide an indication for the use of antimicrobials. Further, sensor embodiments disclosed herein may collect further information in deeper tissue, such as identifying pressure ulcer damage and/or the fatty tissue levels.

The sensor embodiments disclosed herein may be utilized in cardiovascular monitoring. For example, such sensor embodiments may be incorporated into a flexible cardiovascular monitor that may be placed against the skin to monitor characteristics of the cardiovascular system and communicate such information to another device and/or a caregiver. For example, such a device may monitor pulse rate, oxygenation of the blood, and/or electrical activity of the heart. Similarly, the sensor embodiments disclosed herein may be utilized for neurophysiological applications, such as monitoring electrical activity of neurons.

The sensor embodiments disclosed herein may be incorporated into implantable devices, such as implantable orthopedic implants, including flexible implants. Such sensor embodiments may be configured to collect information regarding the implant site and transmit this information to an external source. In some embodiments, an internal source may also provide power for such an implant.

The sensor embodiments disclosed herein may also be utilized for monitoring biochemical activity on the surface of the skin or below the surface of the skin, such as lactose buildup in muscle or sweat production on the surface of the skin. In some embodiments, other characteristics may be monitored, such as glucose concentration, urine concentration, tissue pressure, skin temperature, skin surface conductivity, skin surface resistivity, skin hydration, skin maceration, and/or skin ripping.

Sensor embodiments as disclosed herein may be incorporated into Ear, Nose, and Throat (ENT) applications. For example, such sensor embodiments may be utilized to monitor recovery from ENT-related surgery, such as wound monitoring within the sinus passage.

As described in greater detail below, the sensor embodiments disclosed herein may encompass sensor printing technology with encapsulation, such as encapsulation with a polymer film. Such a film may be constructed using any polymer described herein, such as polyurethane. Encapsulation of the sensor embodiments may provide waterproofing of the electronics and protection from local tissue, local fluids, and other sources of potential damage.

In certain embodiments, the sensors disclosed herein may be incorporated into an organ protection layer such as disclosed below. Such a sensor-embedded organ protection layer may both protect the organ of interest and confirm that the organ protection layer is in position and providing protection. Further, a sensor-embedded organ protection layer may be utilized to monitor the underlying organ, such as by monitoring blood flow, oxygenation, and other suitable markers of organ health. In some embodiments, a sensor-enabled organ protection layer may be used to monitor a transplanted organ, such as by monitoring the fat and muscle content of the organ. Further, sensor-enabled organ protection layers may be used to monitor an organ during and after transplant, such as during rehabilitation of the organ.

The sensor embodiments disclosed herein may be incorporated into treatments for wounds (disclosed in greater detail below) or in a variety of other applications. Non-limiting examples of additional applications for the sensor embodiments disclosed herein include: monitoring and treatment of intact skin, cardiovascular applications such as monitoring blood flow, orthopedic applications such as monitoring limb movement and bone repair, neurophysiological applications such as monitoring electrical impulses, and any other tissue, organ, system, or condition that may benefit from improved sensor-enabled monitoring.

Wound Therapy

Some embodiments disclosed herein relate to wound therapy for a human or animal body. Therefore, any reference to a wound herein can refer to a wound on a human or animal body, and any reference to a body herein can refer to a human or animal body. The disclosed technology embodiments may relate to preventing or minimizing damage to physiological tissue or living tissue, or to the treatment of damaged tissue (for example, a wound as described herein) wound with or without reduced pressure, including for example a source of negative pressure and wound dressing components and apparatuses. The apparatuses and components comprising the wound overlay and packing materials or internal layers, if any, are sometimes collectively referred to herein as dressings. In some embodiments, the wound dressing can be provided to be utilized without reduced pressure.

Some embodiments disclosed herein relate to wound therapy for a human or animal body. Therefore, any reference to a wound herein can refer to a wound on a human or animal body, and any reference to a body herein can refer to a human or animal body. The disclosed technology embodiments may relate to preventing or minimizing damage to physiological tissue or living tissue, or to the treatment of damaged tissue (for example, a wound as described herein).

As used herein the expression “wound” may include an injury to living tissue may be caused by a cut, blow, or other impact, typically one in which the skin is cut or broken. A wound may be a chronic or acute injury. Acute wounds occur as a result of surgery or trauma. They move through the stages of healing within a predicted timeframe. Chronic wounds typically begin as acute wounds. The acute wound can become a chronic wound when it does not follow the healing stages resulting in a lengthened recovery. It is believed that the transition from acute to chronic wound can be due to a patient being immuno-compromised.

Chronic wounds may include for example: venous ulcers (such as those that occur in the legs), which account for the majority of chronic wounds and mostly affect the elderly, diabetic ulcers (for example, foot or ankle ulcers), peripheral arterial disease, pressure ulcers, or epidermolysis bullosa (EB).

Examples of other wounds include, but are not limited to, abdominal wounds or other large or incisional wounds, either as a result of surgery, trauma, sternotomies, fasciotomies, or other conditions, dehisced wounds, acute wounds, chronic wounds, subacute and dehisced wounds, traumatic wounds, flaps and skin grafts, lacerations, abrasions, contusions, burns, diabetic ulcers, pressure ulcers, stoma, surgical wounds, trauma and venous ulcers or the like.

Wounds may also include a deep tissue injury. Deep tissue injury is a term proposed by the National Pressure Ulcer Advisory Panel (NPUAP) to describe a unique form of pressure ulcers. These ulcers have been described by clinicians for many years with terms such as purple pressure ulcers, ulcers that are likely to deteriorate and bruises on bony prominences.

Wound may also include tissue at risk of becoming a wound as discussed herein. For example, tissue at risk may include tissue over a bony protuberance (at risk of deep tissue injury/insult) or pre-surgical tissue (for example, knee tissue) that may have the potential to be cut (for example, for joint replacement/surgical alteration/reconstruction).

Some embodiments relate to methods of treating a wound with the technology disclosed herein in conjunction with one or more of the following: advanced footwear, turning a patient, offloading (such as, offloading diabetic foot ulcers),

treatment of infection, systemics, antimicrobial, antibiotics, surgery, removal of tissue, affecting blood flow, physiotherapy, exercise, bathing, nutrition, hydration, nerve stimulation, ultrasound, electrostimulation, oxygen therapy, microwave therapy, active agents ozone, antibiotics, antimicrobials, or the like.

Alternatively or additionally, a wound may be treated using topical negative pressure and/or traditional advanced wound care, which is not aided by the using of applied negative pressure (may also be referred to as non-negative pressure therapy).

Advanced wound care may include use of an absorbent dressing, an occlusive dressing, use of an antimicrobial and/or debriding agents in a wound dressing or adjunct, a pad (for example, a cushioning or compressive therapy, such as stockings or bandages), or the like.

In some embodiments, treatment of such wounds can be performed using traditional wound care, wherein a dressing can be applied to the wound to facilitate and promote healing of the wound.

Some embodiments relate to methods of manufacturing a wound dressing comprising providing a wound dressing as disclosed herein.

The wound dressings that may be utilized in conjunction with the disclosed technology include any known dressing in the art. The technology is applicable to negative pressure therapy treatment as well as non-negative pressure therapy treatment.

In some embodiments, a wound dressing comprises one or more absorbent layer(s). The absorbent layer may be a foam or a superabsorbent.

In some embodiments, wound dressings may comprise a dressing layer including a polysaccharide or modified polysaccharide, a polyvinylpyrrolidone, a polyvinyl alcohol, a polyvinyl ether, a polyurethane, a polyacrylate, a polyacrylamide, collagen, or gelatin or mixtures thereof. Dressing layers comprising the polymers listed are known in the art as being useful for forming a wound dressing layer for either negative pressure therapy or non-negative pressure therapy.

In some embodiments, the polymer matrix may be a polysaccharide or modified polysaccharide.

In some embodiments, the polymer matrix may be a cellulose. Cellulose material may include hydrophilically modified cellulose such as methyl cellulose, carboxymethyl cellulose (CMC), carboxymethyl cellulose (CEC), ethyl cellulose, propyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, carboxyethyl sulphonate cellulose, cellulose alkyl sulphonate, or mixtures thereof.

In certain embodiments, cellulose material may be cellulose alkyl sulphonate. The alkyl moiety of the alkyl sulphonate substituent group may have an alkyl group having 1 to 6 carbon atoms, such as methyl, ethyl, propyl, or butyl. The alkyl moiety may be branched or unbranched, and hence suitable propyl sulphonate substituents may be 1- or 2-methyl-ethylsulphonate. Butyl sulphonate substituents may be 2-ethyl-ethylsulphonate, 2,2-dimethyl-ethylsulphonate, or 1,2-dimethyl-ethylsulphonate. The alkyl sulphonate substituent group may be ethyl sulphonate. The cellulose alkyl sulphonate is described in WO10061225, US2016/114074, US2006/0142560, or U.S. Pat. No. 5,703,225, the disclosures of which are hereby incorporated by reference in their entirety.

Cellulose alkyl sulfonates may have varying degrees of substitution, the chain length of the cellulose backbone structure, and the structure of the alkyl sulfonate substituent. Solubility and absorbency are largely dependent on the

degree of substitution: as the degree of substitution is increased, the cellulose alkyl sulfonate becomes increasingly soluble. It follows that, as solubility increases, absorbency increases.

In some embodiments, a wound dressing also comprises a top or cover layer.

The thickness of the wound dressing disclosed herein may be between 1 to 20, or 2 to 10, or 3 to 7 mm.

In some embodiments, the disclosed technology may be used in conjunction with a non-negative pressure dressing. A non-negative pressure wound dressing suitable for providing protection at a wound site may comprise:

an absorbent layer for absorbing wound exudate and an obscuring element for at least partially obscuring a view of wound exudate absorbed by the absorbent layer in use.

The obscuring element may be partially translucent.

The obscuring element may be a masking layer.

The non-negative pressure wound dressing may further comprise a region in or adjacent the obscuring element for allowing viewing of the absorbent layer. For example, the obscuring element layer may be provided over a central region of the absorbent layer and not over a border region of the absorbent layer. In some embodiments, the obscuring element is of hydrophilic material or is coated with a hydrophilic material.

The obscuring element may comprise a three-dimensional knitted spacer fabric. The spacer fabric is known in the art and may include a knitted spacer fabric layer.

The obscuring element may further comprise an indicator for indicating the need to change the dressing.

In some embodiments, the obscuring element is provided as a layer at least partially over the absorbent layer, further from a wound site than the absorbent layer in use.

The non-negative pressure wound dressing may further comprise a plurality of openings in the obscuring element for allowing fluid to move therethrough. The obscuring element may comprise, or may be coated with, a material having size-exclusion properties for selectively permitting or preventing passage of molecules of a predetermined size or weight.

The obscuring element may be configured to at least partially mask light radiation having wavelength of 600 nm and less.

The obscuring element may be configured to reduce light absorption by 50% or more.

The obscuring element may be configured to yield a CIE L* value of 50 or more, and optionally 70 or more. In some embodiments, the obscuring element may be configured to yield a CIE L* value of 70 or more.

In some embodiments, the non-negative pressure wound dressing may further comprise at least one of a wound contact layer, a foam layer, an odor control element, a pressure-resistant layer and a cover layer.

In some embodiments, the cover layer is present, and the cover layer is a translucent film. Typically, the translucent film has a moisture vapour permeability of 500 g/m²/24 hours or more.

The translucent film may be a bacterial barrier.

In some embodiments, the non-negative pressure wound dressing as disclosed herein comprises the wound contact layer and the absorbent layer overlies the wound contact layer. The wound contact layer carries an adhesive portion for forming a substantially fluid tight seal over the wound site.

The non-negative pressure wound dressing as disclosed herein may comprise the obscuring element and the absorbent layer being provided as a single layer.

In some embodiments, the non-negative pressure wound dressing disclosed herein comprises the foam layer, and the obscuring element is of a material comprising components that may be displaced or broken by movement of the obscuring element.

In some embodiments, the non-negative pressure wound dressing comprises an odor control element, and in another embodiment the dressing does not include an odor control element. When present, the odor control element may be dispersed within or adjacent the absorbent layer or the obscuring element. Alternatively, when present the odor control element may be provided as a layer sandwiched between the foam layer and the absorbent layer.

In some embodiments, the disclosed technology for a non-negative pressure wound dressing comprises a method of manufacturing a wound dressing, comprising: providing an absorbent layer for absorbing wound exudate; and providing an obscuring element for at least partially obscuring a view of wound exudate absorbed by the absorbent layer in use.

In some embodiments, the non-negative pressure wound dressing is may be suitable for providing protection at a wound site, comprising: an absorbent layer for absorbing wound exudate; and a shielding layer provided over the absorbent layer, and further from a wound-facing side of the wound dressing than the absorbent layer. The shielding layer may be provided directly over the absorbent layer. In some embodiments, the shielding layer comprises a three-dimensional spacer fabric layer.

The shielding layer increases the area over which a pressure applied to the dressing is transferred by 25% or more or the initial area of application. For example, the shielding layer increases the area over which a pressure applied to the dressing is transferred by 50% or more, and optionally by 100% or more, and optionally by 200% or more.

The shielding layer may comprise 2 or more sub-layers, wherein a first sub-layer comprises through holes and a further sub-layer comprises through holes and the through holes of the first sub-layer are offset from the through holes of the further sub-layer.

The non-negative pressure wound dressing as disclosed herein may further comprise a permeable cover layer for allowing the transmission of gas and vapour therethrough, the cover layer provided over the shielding layer, wherein through holes of the cover layer are offset from through holes of the shielding layer.

The non-negative pressure wound dressing may be suitable for treatment of pressure ulcers.

A more detailed description of the non-negative pressure wound dressing disclosed hereinabove is provided in WO2013007973, the entirety of which is hereby incorporated by reference.

In some embodiments, the non-negative pressure wound dressing may be a multi-layered wound dressing comprising: a fibrous absorbent layer for absorbing exudate from a wound site; and a support layer configured to reduce shrinkage of at least a portion of the wound dressing.

In some embodiments, the multi-layered wound dressing disclosed herein, further comprises a liquid impermeable film layer, wherein the support layer is located between the absorbent layer and the film layer.

The support layer disclosed herein may comprise a net. The net may comprise a geometric structure having a

plurality of substantially geometric apertures extending therethrough. The geometric structure may for example comprise a plurality of bosses substantially evenly spaced and joined by polymer strands to form the substantially geometric apertures between the polymer strands.

The net may be formed from high density polyethylene.

The apertures may have an area from 0.005 to 0.32 mm².

The support layer may have a tensile strength from 0.05 to 0.06 Nm.

The support layer may have a thickness of from 50 to 150 μm.

In some embodiments, the support layer is located directly adjacent the absorbent layer. Typically, the support layer is bonded to fibers in a top surface of the absorbent layer. The support layer may further comprise a bonding layer, wherein the support layer is heat laminated to the fibers in the absorbent layer via the bonding layer. The bonding layer may comprise a low melting point adhesive such as ethylene-vinyl acetate adhesive.

In some embodiments, the multi-layered wound dressing disclosed herein further comprises an adhesive layer attaching the film layer to the support layer.

In some embodiments, the multi-layered wound dressing disclosed herein further comprises a wound contact layer located adjacent the absorbent layer for positioning adjacent a wound. The multi-layered wound dressing may further comprise a fluid transport layer between the wound contact layer and the absorbent layer for transporting exudate away from a wound into the absorbent layer.

A more detailed description of the multi-layered wound dressing disclosed hereinabove is provided in GB patent application filed on 28 Oct. 2016 with application number GB1618298.2, the entirety of which is hereby incorporated by reference.

In some embodiments, the disclosed technology may be incorporated in a wound dressing comprising a vertically lapped material comprising: a first layer of an absorbing layer of material, and a second layer of material, wherein the first layer being constructed from at least one layer of non-woven textile fibers, the non-woven textile fibers being folded into a plurality of folds to form a pleated structure. In some embodiments, the wound dressing further comprises a second layer of material that is temporarily or permanently connected to the first layer of material.

Typically the vertically lapped material has been slitted.

In some embodiments, the first layer has a pleated structure having a depth determined by the depth of pleats or by the slitting width. The first layer of material may be a moldable, lightweight, fiber-based material, blend of material or composition layer.

The first layer of material may comprise one or more of manufactured fibers from synthetic, natural or inorganic polymers, natural fibers of a cellulosic, proteinaceous or mineral source.

The wound dressing may comprise two or more layers of the absorbing layer of material vertically lapped material stacked one on top of the other, wherein the two or more layers have the same or different densities or composition.

The wound dressing may in some embodiments comprise only one layer of the absorbing layer of material vertically lapped material.

The absorbing layer of material is a blend of natural or synthetic, organic or inorganic fibers, and binder fibers, or bicomponent fibers typically PET with a low melt temperature PET coating to soften at specified temperatures and to act as a bonding agent in the overall blend.

In some embodiments, the absorbing layer of material may be a blend of 5 to 95% thermoplastic polymer, and 5 to 95 wt % of a cellulose or derivative thereof.

In some embodiments, the wound dressing disclosed herein has a second layer comprises a foam or a dressing fixative.

The foam may be a polyurethane foam. The polyurethane foam may have an open or closed pore structure.

The dressing fixative may include bandages, tape, gauze, or backing layer.

In some embodiments, the wound dressing as disclosed herein comprises the absorbing layer of material connected directly to a second layer by lamination or by an adhesive, and the second layer is connected to a dressing fixative layer. The adhesive may be an acrylic adhesive, or a silicone adhesive.

In some embodiments, the wound dressing as disclosed herein further comprises layer of a superabsorbent fiber, or a viscose fiber or a polyester fiber.

In some embodiments, the wound dressing as disclosed herein further comprises a backing layer. The backing layer may be a transparent or opaque film. Typically, the backing layer comprises a polyurethane film (typically a transparent polyurethane film).

A more detailed description of the multi-layered wound dressing disclosed hereinabove is provided in GB patent applications filed on 12 Dec. 2016 with application number GB1621057.7; and 22 Jun. 2017 with application number GB1709987.0, the entirety of each of which is hereby incorporated by reference.

In some embodiments, the non-negative pressure wound dressing may comprise an absorbent component for a wound dressing, the component comprising a wound contacting layer comprising gel forming fibers bound to a foam layer, wherein the foam layer is bound directly to the wound contact layer by an adhesive, polymer based melt layer, by flame lamination or by ultrasound.

The absorbent component may be in a sheet form.

The wound contacting layer may comprise a layer of woven or non-woven or knitted gel forming fibers.

The foam layer may be an open cell foam, or closed cell foam, typically an open cell foam. The foam layer is a hydrophilic foam.

The wound dressing may comprise the component that forms an island in direct contact with the wound surrounded by periphery of adhesive that adheres the dressing to the wound. The adhesive may be a silicone or acrylic adhesive, typically a silicone adhesive.

The wound dressing may be covered by a film layer on the surface of the dressing furthest from the wound.

A more detailed description of the wound dressing of this type hereinabove is provided in EP2498829, the entirety of which is hereby incorporated by reference.

In some embodiments, the non-negative pressure wound dressing may comprise a multi layered wound dressing for use on wounds producing high levels of exudate, characterized in that the dressing comprising: a transmission layer having an MVTR of at least 300 gm²/24 hours, an absorbent core comprising gel forming fibers capable of absorbing and retaining exudate, a wound contacting layer comprising gel forming fibers which transmits exudate to the absorbent core and a keying layer positioned on the absorbent core, the absorbent core and wound contacting layer limiting the lateral spread of exudate in the dressing to the region of the wound.

The wound dressing may be capable of handling at least 6 g (or 8 g and 15 g) of fluid per 10 cm² of dressing in 24 hours.

The wound dressing may comprise gel forming fibers that are chemically modified cellulosic fibers in the form of a fabric. The fibers may include carboxymethylated cellulose fibers, typically sodium carboxymethylcellulose fiber.

The wound dressing may comprise a wound contact layer with a lateral wicking rate from 5 mm per minute to 40 mm per minute. The wound contact layer may have a fiber density between 25 gm² and 55 gm², such as 35 gm².

The absorbent core may have an absorbency of exudate of at least 10 g/g, and typically a rate of lateral wicking of less than 20 mm per minute.

The absorbent core may have a blend in the range of up to 25% cellulosic fibers by weight and 75% to 100% gel forming fibers by weight.

Alternatively, the absorbent core may have a blend in the range of up to 50% cellulosic fibers by weight and 50% to 100% gel forming fibers by weight. For example, the blend is in the range of 50% cellulosic fibers by weight and 50% gel forming fibers by weight.

The fiber density in the absorbent core may be between 150 gm² and 250 gm², or about 200 gm².

The wound dressing when wet may have shrinkage that is less than 25% or less than 15% of its original size/dimension.

The wound dressing may comprise a transmission layer and the layer is a foam. The transmission layer may be a polyurethane foam laminated to a polyurethane film.

The wound dressing may comprise one or more layers selected from the group comprising a soluble medicated film layer; an odor-absorbing layer; a spreading layer and an additional adhesive layer.

The wound dressing may be 2 mm and 4 mm thick.

The wound dressing may be characterized in that the keying layer bonds the absorbent core to a neighboring layer. In some embodiments, the keying layer may be positioned on either the wound facing side of the absorbent core or the non-wound facing side of the absorbent core. In some embodiments, the keying layer is positioned between the absorbent core and the wound contact layer. The keying layer is a polyamide web.

A more detailed description of the wound dressing of this type hereinabove is provided in EP1718257, the entirety of which is hereby incorporated by reference.

In some embodiments, the non-negative pressure wound dressing may be a compression bandage. Compression bandages are known for use in the treatment of oedema and other venous and lymphatic disorders, e.g., of the lower limbs.

A compression bandage systems typically employ multiple layers including a padding layer between the skin and the compression layer or layers. The compression bandage may be useful for wounds such as handling venous leg ulcers.

The compression bandage in some embodiments may comprise a bandage system comprising an inner skin facing layer and an elastic outer layer, the inner layer comprising a first ply of foam and a second ply of an absorbent nonwoven web, the inner layer and outer layer being sufficiently elongated so as to be capable of being wound about a patient's limb. A compression bandage of this type is disclosed in WO99/58090, the entirety of which is hereby incorporated by reference.

In some embodiments, the compression bandage system comprises: a) an inner skin facing, elongated, elastic bandage comprising: (i) an elongated, elastic substrate, and

(ii) an elongated layer of foam, said foam layer being affixed to a face of said substrate and extending 33% or more across said face of substrate in transverse direction and 67% or more across said face of substrate in longitudinal direction; and b) an outer, elongated, self-adhering elastic bandage; said bandage having a compressive force when extended; wherein, in use, said foam layer of the inner bandage faces the skin and the outer bandage overlies the inner bandage. A compression bandage of this type is disclosed in WO2006/110527, the entirety of which is hereby incorporated by reference.

In some embodiments other compression bandage systems such as those disclosed in U.S. Pat. No. 6,759,566 and US 2002/0099318, the entirety of each of which is hereby incorporated by reference.

Negative Pressure Wound Dressing

In some embodiments, treatment of such wounds can be performed using negative pressure wound therapy, wherein a reduced or negative pressure can be applied to the wound to facilitate and promote healing of the wound. It will also be appreciated that the wound dressing and methods as disclosed herein may be applied to other parts of the body, and are not necessarily limited to treatment of wounds.

It will be understood that embodiments of the present disclosure are generally applicable to use in topical negative pressure ("TNP") therapy systems. Briefly, negative pressure wound therapy assists in the closure and healing of many forms of "hard to heal" wounds by reducing tissue oedema; encouraging blood flow and granular tissue formation; removing excess exudate and may reduce bacterial load (and thus infection risk). In addition, the therapy allows for less disturbance of a wound leading to more rapid healing. TNP therapy systems may also assist on the healing of surgically closed wounds by removing fluid and by helping to stabilize the tissue in the apposed position of closure. A further beneficial use of TNP therapy can be found in grafts and flaps where removal of excess fluid is important and close proximity of the graft to tissue is required in order to ensure tissue viability.

Negative pressure therapy can be used for the treatment of open or chronic wounds that are too large to spontaneously close or otherwise fail to heal by means of applying negative pressure to the site of the wound. Topical negative pressure (TNP) therapy or negative pressure wound therapy (NPWT) involves placing a cover that is impermeable or semi-permeable to fluids over the wound, using various means to seal the cover to the tissue of the patient surrounding the wound, and connecting a source of negative pressure (such as a vacuum pump) to the cover in a manner so that negative pressure is created and maintained under the cover. It is believed that such negative pressures promote wound healing by facilitating the formation of granulation tissue at the wound site and assisting the body's normal inflammatory process while simultaneously removing excess fluid, which may contain adverse cytokines or bacteria.

Some of the dressings used in NPWT can include many different types of materials and layers, for example, gauze, pads, foam pads or multi-layer wound dressings. One example of a multi-layer wound dressing is the PICO dressing, available from Smith & Nephew, includes a wound contact layer and a superabsorbent layer beneath a backing layer to provide a canister-less system for treating a wound with NPWT. The wound dressing may be sealed to a suction port providing connection to a length of tubing, which may

be used to pump fluid out of the dressing or to transmit negative pressure from a pump to the wound dressing. Additionally, RENASYS-F, RENASYS-G, RENASYS-AB, and RENASYS-F/AB, available from Smith & Nephew, are additional examples of NPWT wound dressings and systems. Another example of a multi-layer wound dressing is the ALLEVYN Life dressing, available from Smith & Nephew, which includes a moist wound environment dressing that is used to treat the wound without the use of negative pressure.

As is used herein, reduced or negative pressure levels, such as $-X$ mmHg, represent pressure levels relative to normal ambient atmospheric pressure, which can correspond to 760 mmHg (or 1 atm, 29.93 inHg, 101.325 kPa, 14.696 psi, etc.). Accordingly, a negative pressure value of $-X$ mmHg reflects absolute pressure that is X mmHg below 760 mmHg or, in other words, an absolute pressure of $(760-X)$ mmHg. In addition, negative pressure that is “less” or “smaller” than X mmHg corresponds to pressure that is closer to atmospheric pressure (such as, -40 mmHg is less than -60 mmHg). Negative pressure that is “more” or “greater” than $-X$ mmHg corresponds to pressure that is further from atmospheric pressure (such as, -80 mmHg is more than -60 mmHg). In some embodiments, local ambient atmospheric pressure is used as a reference point, and such local atmospheric pressure may not necessarily be, for example, 760 mmHg.

The negative pressure range for some embodiments of the present disclosure can be approximately -80 mmHg, or between about -20 mmHg and -200 mmHg. Note that these pressures are relative to normal ambient atmospheric pressure, which can be 760 mmHg. Thus, -200 mmHg would be about 560 mmHg in practical terms. In some embodiments, the pressure range can be between about -40 mmHg and -150 mmHg. Alternatively, a pressure range of up to -75 mmHg, up to -80 mmHg or over -80 mmHg can be used. Also in other embodiments a pressure range of below -75 mmHg can be used. Alternatively, a pressure range of over approximately -100 mmHg, or even -150 mmHg, can be supplied by the negative pressure apparatus.

In some embodiments of wound closure devices described herein, increased wound contraction can lead to increased tissue expansion in the surrounding wound tissue. This effect may be increased by varying the force applied to the tissue, for example by varying the negative pressure applied to the wound over time, possibly in conjunction with increased tensile forces applied to the wound via embodiments of the wound closure devices. In some embodiments, negative pressure may be varied over time for example using a sinusoidal wave, square wave, or in synchronization with one or more patient physiological indices (such as, heart-beat). Examples of such applications where additional disclosure relating to the preceding may be found include U.S. Pat. No. 8,235,955, titled “Wound treatment apparatus and method,” issued on Aug. 7, 2012; and U.S. Pat. No. 7,753,894, titled “Wound cleansing apparatus with stress,” issued Jul. 13, 2010. The disclosures of both of these patents are hereby incorporated by reference in their entirety.

Embodiments of the wound dressings, wound dressing components, wound treatment apparatuses and methods described herein may also be used in combination or in addition to those described in International Application No. PCT/IB2013/001469, filed May 22, 2013, published as WO 2013/175306 A2 on Nov. 28, 2013, titled “APPARATUSES AND METHODS FOR NEGATIVE PRESSURE WOUND THERAPY,” U.S. patent application Ser. No. 14/418,908, filed Jan. 30, 2015, published as US 2015/0190286 A1 on

Jul. 9, 2015, titled “WOUND DRESSING AND METHOD OF TREATMENT,” the disclosures of which are hereby incorporated by reference in their entirety. Embodiments of the wound dressings, wound dressing components, wound treatment apparatuses and methods described herein may also be used in combination or in addition to those described in U.S. patent application Ser. No. 13/092,042, filed Apr. 21, 2011, published as US2011/0282309, titled “WOUND DRESSING AND METHOD OF USE,” and U.S. patent application Ser. No. 14/715,527, filed May 18, 2015, published as US2016/0339158 A1 on Nov. 24, 2016, titled “FLUIDIC CONNECTOR FOR NEGATIVE PRESSURE WOUND THERAPY,” the disclosure of each of which is hereby incorporated by reference in its entirety, including further details relating to embodiments of wound dressings, the wound dressing components and principles, and the materials used for the wound dressings.

Additionally, some embodiments related to TNP wound treatment comprising a wound dressing in combination with a pump or associated electronics described herein may also be used in combination or in addition to those described in International Application PCT/EP2016/059329 filed Apr. 26, 2016, published as WO 2016/174048 on Nov. 3, 2016, entitled “REDUCED PRESSURE APPARATUS AND METHODS,” the disclosure of which is hereby incorporated by reference in its entirety. NPWT System Overview

FIG. 1A illustrates an embodiment of a negative or reduced pressure wound treatment (or TNP) system **100** comprising a wound filler **130** placed inside a wound cavity **110**, the wound cavity sealed by a wound cover **120**. The wound filler **130** in combination with the wound cover **120** can be referred to as wound dressing. A single or multi lumen tube or conduit **140** is connected to the wound cover **120** with a pump assembly **150** configured to supply reduced pressure. The wound cover **120** can be in fluidic communication with the wound cavity **110**. In any of the system embodiments disclosed herein, as in the embodiment illustrated in FIG. 1, the pump assembly can be a canisterless pump assembly (meaning that exudate is collected in the wound dressing or is transferred via tube **140** for collection to another location). However, any of the pump assembly embodiments disclosed herein can be configured to include or support a canister. Additionally, in any of the system embodiments disclosed herein, any of the pump assembly embodiments can be mounted to or supported by the dressing, or adjacent to the dressing.

The wound filler **130** can be any suitable type, such as hydrophilic or hydrophobic foam, gauze, inflatable bag, and so on. The wound filler **130** can be conformable to the wound cavity **110** such that it substantially fills the cavity. The wound cover **120** can provide a substantially fluid impermeable seal over the wound cavity **110**. The wound cover **120** can have a top side and a bottom side, and the bottom side adhesively (or in any other suitable manner) seals with wound cavity **110**. The conduit **140** or lumen or any other conduit or lumen disclosed herein can be formed from polyurethane, PVC, nylon, polyethylene, silicone, or any other suitable material.

Some embodiments of the wound cover **120** can have a port (not shown) configured to receive an end of the conduit **140**. For example, the port can be Renasys Soft Port available from Smith & Nephew. In other embodiments, the conduit **140** can otherwise pass through or under the wound cover **120** to supply reduced pressure to the wound cavity **110** so as to maintain a desired level of reduced pressure in the wound cavity. The conduit **140** can be any suitable article

configured to provide at least a substantially sealed fluid flow pathway between the pump assembly **150** and the wound cover **120**, so as to supply the reduced pressure provided by the pump assembly **150** to wound cavity **110**.

The wound cover **120** and the wound filler **130** can be provided as a single article or an integrated single unit. In some embodiments, no wound filler is provided and the wound cover by itself may be considered the wound dressing. The wound dressing may then be connected, via the conduit **140**, to a source of negative pressure, such as the pump assembly **150**. The pump assembly **150** can be miniaturized and portable, although larger conventional pumps such can also be used.

The wound cover **120** can be located over a wound site to be treated. The wound cover **120** can form a substantially sealed cavity or enclosure over the wound site. In some embodiments, the wound cover **120** can be configured to have a film having a high water vapour permeability to enable the evaporation of surplus fluid, and can have a superabsorbing material contained therein to safely absorb wound exudate. It will be appreciated that throughout this specification reference is made to a wound. In this sense it is to be understood that the term wound is to be broadly construed and encompasses open and closed wounds in which skin is torn, cut or punctured or where trauma causes a contusion, or any other surficial or other conditions or imperfections on the skin of a patient or otherwise that benefit from reduced pressure treatment. A wound is thus broadly defined as any damaged region of tissue where fluid may or may not be produced. Examples of such wounds include, but are not limited to, acute wounds, chronic wounds, surgical incisions and other incisions, subacute and dehiscent wounds, traumatic wounds, flaps and skin grafts, lacerations, abrasions, contusions, burns, diabetic ulcers, pressure ulcers, stoma, surgical wounds, trauma and venous ulcers or the like. The components of the TNP system described herein can be particularly suited for incisional wounds that exude a small amount of wound exudate.

Some embodiments of the system are designed to operate without the use of an exudate canister. Some embodiments can be configured to support an exudate canister. In some embodiments, configuring the pump assembly **150** and tubing **140** so that the tubing **140** can be quickly and easily removed from the pump assembly **150** can facilitate or improve the process of dressing or pump changes, if necessary. Any of the pump embodiments disclosed herein can be configured to have any suitable connection between the tubing and the pump.

The pump assembly **150** can be configured to deliver negative pressure of approximately -80 mmHg, or between about -20 mmHg and 200 mmHg in some implementations. Note that these pressures are relative to normal ambient atmospheric pressure thus, -200 mmHg would be about 560 mmHg in practical terms. The pressure range can be between about -40 mmHg and -150 mmHg. Alternatively, a pressure range of up to -75 mmHg, up to -80 mmHg or over -80 mmHg can be used. Also, a pressure range of below -75 mmHg can be used. Alternatively, a pressure range of over approximately -100 mmHg, or even 150 mmHg, can be supplied by the pump assembly **150**.

In operation, the wound filler **130** is inserted into the wound cavity **110** and wound cover **120** is placed so as to seal the wound cavity **110**. The pump assembly **150** provides a source of a negative pressure to the wound cover **120**, which is transmitted to the wound cavity **110** via the wound filler **130**. Fluid (such as, wound exudate) is drawn through the conduit **140**, and can be stored in a canister. In some

embodiments, fluid is absorbed by the wound filler **130** or one or more absorbent layers (not shown).

Wound dressings that may be utilized with the pump assembly and other embodiments of the present application include Renasys-F, Renasys-G, Renasys AB, and Pico Dressings available from Smith & Nephew. Further description of such wound dressings and other components of a negative pressure wound therapy system that may be used with the pump assembly and other embodiments of the present application are found in U.S. Patent Publication Nos. 2011/0213287, 2011/0282309, 2012/0116334, 2012/0136325, and 2013/0110058, which are incorporated by reference in their entirety. In other embodiments, other suitable wound dressings can be utilized.

15 Wound Dressing Overview

FIG. 1B illustrates a cross-section through a wound dressing **155** according to some embodiments. FIG. 1B also illustrates a fluidic connector **160** according to some embodiments. The wound dressing **155** can be similar to the wound dressing described in International Patent Publication WO2013175306 A2, which is incorporated by reference in its entirety. Alternatively, the wound dressing **155** can be any wound dressing embodiment disclosed herein or any combination of features of any number of wound dressing embodiments disclosed herein, can be located over a wound site to be treated. The wound dressing **155** may be placed as to form a sealed cavity over the wound, such as the wound cavity **110**. In some embodiments, the wound dressing **155** includes a top or cover layer, or backing layer **220** attached to an optional wound contact layer **222**, both of which are described in greater detail below. These two layers **220**, **222** can be joined or sealed together so as to define an interior space or chamber. This interior space or chamber may comprise additional structures that may be adapted to distribute or transmit negative pressure, store wound exudate and other fluids removed from the wound, and other functions which will be explained in greater detail below. Examples of such structures, described below, include a transmission layer **226** and an absorbent layer **221**.

As used herein the upper layer, top layer, or layer above refers to a layer furthest from the surface of the skin or wound while the dressing is in use and positioned over the wound. Accordingly, the lower surface, lower layer, bottom layer, or layer below refers to the layer that is closest to the surface of the skin or wound while the dressing is in use and positioned over the wound.

The wound contact layer **222** can be a polyurethane layer or polyethylene layer or other flexible layer which is perforated, for example via a hot pin process, laser ablation process, ultrasound process or in some other way or otherwise made permeable to liquid and gas. The wound contact layer **222** has a lower surface **224** (for example, facing the wound) and an upper surface **223** (for example, facing away from the wound). The perforations **225** can comprise through holes in the wound contact layer **222** which enable fluid to flow through the layer **222**. The wound contact layer **222** helps prevent tissue ingrowth into the other material of the wound dressing. In some embodiments, the perforations are small enough to meet this requirement while still allowing fluid to flow therethrough. For example, perforations formed as slits or holes having a size ranging from 0.025 mm to 1.2 mm are considered small enough to help prevent tissue ingrowth into the wound dressing while allowing wound exudate to flow into the dressing. In some configurations, the wound contact layer **222** may help maintain the integrity of the entire dressing **155** while also creating an air tight seal around the absorbent pad in order to maintain

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negative pressure at the wound. In some embodiments, the wound contact layer is configured to allow unidirectional or substantially one-way or unidirectional flow of fluid through the wound contact layer when negative pressure is applied to the wound. For example, the wound contact layer can permit fluid to flow away from the wound through the wound contact layer, but not allow fluid to flow back toward the wound. In certain case, the perforations in the wound contact layer are configured to permit such one-way or unidirectional flow of fluid through the wound contact layer.

Some embodiments of the wound contact layer **222** may also act as a carrier for an optional lower and upper adhesive layer (not shown). For example, a lower pressure sensitive adhesive may be provided on the lower surface **224** of the wound dressing **155** whilst an upper pressure sensitive adhesive layer may be provided on the upper surface **223** of the wound contact layer. The pressure sensitive adhesive, which may be a silicone, hot melt, hydrocolloid or acrylic based adhesive or other such adhesives, may be formed on both sides or optionally on a selected one or none of the sides of the wound contact layer. When a lower pressure sensitive adhesive layer is utilized may be helpful to adhere the wound dressing **155** to the skin around a wound site. In some embodiments, the wound contact layer may comprise perforated polyurethane film. The lower surface of the film may be provided with a silicone pressure sensitive adhesive and the upper surface may be provided with an acrylic pressure sensitive adhesive, which may help the dressing maintain its integrity. In some embodiments, a polyurethane film layer may be provided with an adhesive layer on both its upper surface and lower surface, and all three layers may be perforated together.

A layer **226** of porous material can be located above the wound contact layer **222**. This porous layer, or transmission layer, **226** allows transmission of fluid including liquid and gas away from a wound site into upper layers of the wound dressing. In particular, the transmission layer **226** can ensure that an open air channel can be maintained to communicate negative pressure over the wound area even when the absorbent layer has absorbed substantial amounts of exudates. The layer **226** can remain open under the typical pressures that will be applied during negative pressure wound therapy as described above, so that the whole wound site sees an equalized negative pressure. The layer **226** may be formed of a material having a three-dimensional structure. For example, a knitted or woven spacer fabric (for example Baltex 7970 weft knitted polyester) or a non-woven fabric could be used.

In some embodiments, the transmission layer **226** comprises a 3D polyester spacer fabric layer including a top layer (that is to say, a layer distal from the wound-bed in use) which is a 84/144 textured polyester, and a bottom layer (that is to say, a layer which lies proximate to the wound bed in use) which is a 10 denier flat polyester and a third layer formed sandwiched between these two layers which is a region defined by a knitted polyester viscose, cellulose or the like monofilament fiber. Other materials and other linear mass densities of fiber could of course be used.

Whilst reference is made throughout this disclosure to a monofilament fiber it will be appreciated that a multistrand alternative could of course be utilized. The top spacer fabric thus has more filaments in a yarn used to form it than the number of filaments making up the yarn used to form the bottom spacer fabric layer.

This differential between filament counts in the spaced apart layers helps control moisture flow across the transmission layer. Particularly, by having a filament count greater in

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the top layer, that is to say, the top layer is made from a yarn having more filaments than the yarn used in the bottom layer, liquid tends to be wicked along the top layer more than the bottom layer. In use, this differential tends to draw liquid away from the wound bed and into a central region of the dressing where the absorbent layer **221** helps lock the liquid away or itself wicks the liquid onwards towards the cover layer where it can be transpired.

In some embodiments, to improve the liquid flow across the transmission layer **226** (that is to say perpendicular to the channel region formed between the top and bottom spacer layers, the 3D fabric may be treated with a dry cleaning agent (such as, but not limited to, Perchloro Ethylene) to help remove any manufacturing products such as mineral oils, fats or waxes used previously which might interfere with the hydrophilic capabilities of the transmission layer. An additional manufacturing step can subsequently be carried in which the 3D spacer fabric is washed in a hydrophilic agent (such as, but not limited to, Feran Ice 30 g/l available from the Rudolph Group). This process step helps ensure that the surface tension on the materials is so low that liquid such as water can enter the fabric as soon as it contacts the 3D knit fabric. This also aids in controlling the flow of the liquid insult component of any exudates.

A layer **221** of absorbent material can be provided above the transmission layer **226**. The absorbent material, which comprise a foam or non-woven natural or synthetic material, and which may optionally comprise a super-absorbent material, forms a reservoir for fluid, particularly liquid, removed from the wound site. In some embodiments, the layer **221** may also aid in drawing fluids towards the backing layer **220**.

The material of the absorbent layer **221** may also prevent liquid collected in the wound dressing **155** from flowing freely within the dressing, and can act so as to contain any liquid collected within the dressing. The absorbent layer **221** also helps distribute fluid throughout the layer via a wicking action so that fluid is drawn from the wound site and stored throughout the absorbent layer. This helps prevent agglomeration in areas of the absorbent layer. The capacity of the absorbent material must be sufficient to manage the exudates flow rate of a wound when negative pressure is applied. Since in use the absorbent layer experiences negative pressures the material of the absorbent layer is chosen to absorb liquid under such circumstances. A number of materials exist that are able to absorb liquid when under negative pressure, for example superabsorber material. The absorbent layer **221** may typically be manufactured from ALLEVYN™ foam, Freudenberg 114-224-4 or Chem-Posite™11C-450. In some embodiments, the absorbent layer **221** may comprise a composite comprising superabsorbent powder, fibrous material such as cellulose, and bonding fibers. In some embodiments, the composite is an airlaid, thermally-bonded composite.

In some embodiments, the absorbent layer **221** is a layer of non-woven cellulose fibers having super-absorbent material in the form of dry particles dispersed throughout. Use of the cellulose fibers introduces fast wicking elements which help quickly and evenly distribute liquid taken up by the dressing. The juxtaposition of multiple strand-like fibers leads to strong capillary action in the fibrous pad which helps distribute liquid. In this way, the super-absorbent material is efficiently supplied with liquid. The wicking action also assists in bringing liquid into contact with the upper cover layer to aid increase transpiration rates of the dressing.

An aperture, hole, or orifice **227** can be provided in the backing layer **220** to allow a negative pressure to be applied to the dressing **155**. In some embodiments, the fluidic connector **160** is attached or sealed to the top of the backing layer **220** over the orifice **227** made into the dressing **155**, and communicates negative pressure through the orifice **227**. A length of tubing may be coupled at a first end to the fluidic connector **160** and at a second end to a pump unit (not shown) to allow fluids to be pumped out of the dressing. Where the fluidic connector is adhered to the top layer of the wound dressing, a length of tubing may be coupled at a first end of the fluidic connector such that the tubing, or conduit, extends away from the fluidic connector parallel or substantially to the top surface of the dressing. The fluidic connector **160** may be adhered and sealed to the backing layer **220** using an adhesive such as an acrylic, cyanoacrylate, epoxy, UV curable or hot melt adhesive. The fluidic connector **160** may be formed from a soft polymer, for example a polyethylene, a polyvinyl chloride, a silicone or polyurethane having a hardness of 30 to 90 on the Shore A scale. In some embodiments, the fluidic connector **160** may be made from a soft or conformable material.

In some embodiments, the absorbent layer **221** includes at least one through hole **228** located so as to underlie the fluidic connector **160**. The through hole **228** may in some embodiments be the same size as the opening **227** in the backing layer, or may be bigger or smaller. As illustrated in FIG. 1B a single through hole can be used to produce an opening underlying the fluidic connector **160**. It will be appreciated that multiple openings could alternatively be utilized. Additionally, should more than one port be utilized according to certain embodiments of the present disclosure one or multiple openings may be made in the absorbent layer and the obscuring layer in registration with each respective fluidic connector. Although not essential to certain embodiments of the present disclosure the use of through holes in the super-absorbent layer may provide a fluid flow pathway which remains unblocked in particular when the absorbent layer is near saturation.

The aperture or through-hole **228** can be provided in the absorbent layer **221** beneath the orifice **227** such that the orifice is connected directly to the transmission layer **226** as illustrated in FIG. 1B. This allows the negative pressure applied to the fluidic connector **160** to be communicated to the transmission layer **226** without passing through the absorbent layer **221**. This ensures that the negative pressure applied to the wound site is not inhibited by the absorbent layer as it absorbs wound exudates. In other embodiments, no aperture may be provided in the absorbent layer **221**, or alternatively a plurality of apertures underlying the orifice **227** may be provided. In further alternative embodiments, additional layers such as another transmission layer or an obscuring layer such as described in International Patent Publication WO2014020440, the entirety of which is hereby incorporated by reference, may be provided over the absorbent layer **221** and beneath the backing layer **220**.

The backing layer **220** is can be gas impermeable, but moisture vapor permeable, and can extend across the width of the wound dressing **155**. The backing layer **220**, which may for example be a polyurethane film (for example, Elastollan SP9109) having a pressure sensitive adhesive on one side, is impermeable to gas and this layer thus operates to cover the wound and to seal a wound cavity over which the wound dressing is placed. In this way an effective chamber is made between the backing layer **220** and a wound site where a negative pressure can be established. The backing layer **220** can be sealed to the wound contact

layer **222** in a border region around the circumference of the dressing, ensuring that no air is drawn in through the border area, for example via adhesive or welding techniques. The backing layer **220** protects the wound from external bacterial contamination (bacterial barrier) and allows liquid from wound exudates to be transferred through the layer and evaporated from the film outer surface. The backing layer **220** can include two layers; a polyurethane film and an adhesive pattern spread onto the film. The polyurethane film can be moisture vapor permeable and may be manufactured from a material that has an increased water transmission rate when wet. In some embodiments the moisture vapor permeability of the backing layer increases when the backing layer becomes wet. The moisture vapor permeability of the wet backing layer may be up to about ten times more than the moisture vapor permeability of the dry backing layer.

The absorbent layer **221** may be of a greater area than the transmission layer **226**, such that the absorbent layer overlaps the edges of the transmission layer **226**, thereby ensuring that the transmission layer does not contact the backing layer **220**. This provides an outer channel of the absorbent layer **221** that is in direct contact with the wound contact layer **222**, which aids more rapid absorption of exudates to the absorbent layer. Furthermore, this outer channel ensures that no liquid is able to pool around the circumference of the wound cavity, which may otherwise seep through the seal around the perimeter of the dressing leading to the formation of leaks. As illustrated in FIG. 1B, the absorbent layer **221** may define a smaller perimeter than that of the backing layer **220**, such that a boundary or border region is defined between the edge of the absorbent layer **221** and the edge of the backing layer **220**.

As shown in FIG. 1B, one embodiment of the wound dressing **155** comprises an aperture **228** in the absorbent layer **221** situated underneath the fluidic connector **160**. In use, for example when negative pressure is applied to the dressing **155**, a wound facing portion of the fluidic connector may thus come into contact with the transmission layer **226**, which can thus aid in transmitting negative pressure to the wound site even when the absorbent layer **221** is filled with wound fluids. Some embodiments may have the backing layer **220** be at least partly adhered to the transmission layer **226**. In some embodiments, the aperture **228** is at least 1-2 mm larger than the diameter of the wound facing portion of the fluidic connector **11**, or the orifice **227**.

For example, in embodiments with a single fluidic connector **160** and through hole, it may be preferable for the fluidic connector **160** and through hole to be located in an off-center position. Such a location may permit the dressing **155** to be positioned onto a patient such that the fluidic connector **160** is raised in relation to the remainder of the dressing **155**. So positioned, the fluidic connector **160** and the filter **214** may be less likely to come into contact with wound fluids that could prematurely occlude the filter **214** so as to impair the transmission of negative pressure to the wound site.

Turning now to the fluidic connector **160**, some embodiments include a sealing surface **216**, a bridge **211** with a proximal end (closer to the negative pressure source) and a distal end **140**, and a filter **214**. The sealing surface **216** can form the applicator that is sealed to the top surface of the wound dressing. In some embodiments a bottom layer of the fluidic connector **160** may comprise the sealing surface **216**. The fluidic connector **160** may further comprise an upper surface vertically spaced from the sealing surface **216**, which in some embodiments is defined by a separate upper layer of the fluidic connector. In other embodiments the

upper surface and the lower surface may be formed from the same piece of material. In some embodiments the sealing surface **216** may comprise at least one aperture **229** therein to communicate with the wound dressing. In some embodiments the filter **214** may be positioned across the opening **229** in the sealing surface, and may span the entire opening **229**. The sealing surface **216** may be configured for sealing the fluidic connector to the cover layer of the wound dressing, and may comprise an adhesive or weld. In some embodiments, the sealing surface **216** may be placed over an orifice in the cover layer with optional spacer elements **215** configured to create a gap between the filter **214** and the transmission layer **226**. In other embodiments, the sealing surface **216** may be positioned over an orifice in the cover layer and an aperture in the absorbent layer **220**, permitting the fluidic connector **160** to provide air flow through the transmission layer **226**. In some embodiments, the bridge **211** may comprise a first fluid passage **212** in communication with a source of negative pressure, the first fluid passage **212** comprising a porous material, such as a 3D knitted material, which may be the same or different than the porous layer **226** described previously. The bridge **211** can be encapsulated by at least one flexible film layer **208**, **210** having a proximal and distal end and configured to surround the first fluid passage **212**, the distal end of the flexible film being connected the sealing surface **216**. The filter **214** is configured to substantially prevent wound exudate from entering the bridge, and spacer elements **215** are configured to prevent the fluidic connector from contacting the transmission layer **226**. These elements will be described in greater detail below.

Some embodiments may further comprise an optional second fluid passage positioned above the first fluid passage **212**. For example, some embodiments may provide for an air leak may be disposed at the proximal end of the top layer that is configured to provide an air path into the first fluid passage **212** and dressing **155** similar to the suction adapter as described in U.S. Pat. No. 8,801,685, which is incorporated by reference herein in its entirety.

In some embodiment, the fluid passage **212** is constructed from a compliant material that is flexible and that also permits fluid to pass through it if the spacer is kinked or folded over. Suitable materials for the fluid passage **212** include without limitation foams, including open-cell foams such as polyethylene or polyurethane foam, meshes, 3D knitted fabrics, non-woven materials, and fluid channels. In some embodiments, the fluid passage **212** may be constructed from materials similar to those described above in relation to the transmission layer **226**. Advantageously, such materials used in the fluid passage **212** not only permit greater patient comfort, but may also provide greater kink resistance, such that the fluid passage **212** is still able to transfer fluid from the wound toward the source of negative pressure while being kinked or bent.

In some embodiments, the fluid passage **212** may be comprised of a wicking fabric, for example a knitted or woven spacer fabric (such as a knitted polyester 3D fabric, Baltex 7970®), or Gehring 879®) or a nonwoven fabric. These materials selected can be suited to channeling wound exudate away from the wound and for transmitting negative pressure or vented air to the wound site, and may also confer a degree of kinking or occlusion resistance to the fluid passage **212**. In some embodiments, the wicking fabric may have a three-dimensional structure, which in some cases may aid in wicking fluid or transmitting negative pressure. In certain embodiments, including wicking fabrics, these materials remain open and capable of communicating nega-

tive pressure to a wound area under the typical pressures used in negative pressure therapy, for example between -40 to -150 mmHg. In some embodiments, the wicking fabric may comprise several layers of material stacked or layered over each other, which may in some cases be useful in preventing the fluid passage **212** from collapsing under the application of negative pressure. In other embodiments, the wicking fabric used in the fluid passage **212** may be between 1.5 mm and 6 mm; more preferably, the wicking fabric may be between 3 mm and 6 mm thick, and may be comprised of either one or several individual layers of wicking fabric. In other embodiments, the fluid passage **212** may be between 1.2-3 mm thick, and preferably thicker than 1.5 mm. Some embodiments, for example a suction adapter used with a dressing which retains liquid such as wound exudate, may employ hydrophobic layers in the fluid passage **212**, and only gases may travel through the fluid passage **212**. Additionally, and as described previously, the materials used in the system can be conformable and soft, which may help to avoid pressure ulcers and other complications which may result from a wound treatment system being pressed against the skin of a patient.

In some embodiments, the filter element **214** is impermeable to liquids, but permeable to gases, and is provided to act as a liquid barrier and to ensure that no liquids are able to escape from the wound dressing **155**. The filter element **214** may also function as a bacterial barrier. Typically, the pore size is 0.2 μm . Suitable materials for the filter material of the filter element **214** include 0.2 micron Gore™ expanded PTFE from the MMT range, PALL Versapore™ 200R, and Donaldson™ TX6628. Larger pore sizes can also be used but these may require a secondary filter layer to ensure full bioburden containment. As wound fluid contains lipids it is preferable, though not essential, to use an oleophobic filter membrane for example 1.0 micron MMT-332 prior to 0.2 micron MMT-323. This prevents the lipids from blocking the hydrophobic filter. The filter element can be attached or sealed to the port or the cover film over the orifice. For example, the filter element **214** may be molded into the fluidic connector **160**, or may be adhered to one or both of the top of the cover layer and bottom of the suction adapter **160** using an adhesive such as, but not limited to, a UV cured adhesive.

It will be understood that other types of material could be used for the filter element **214**. More generally a microporous membrane can be used which is a thin, flat sheet of polymeric material, this contains billions of microscopic pores. Depending upon the membrane chosen these pores can range in size from 0.01 to more than 10 micrometers. Microporous membranes are available in both hydrophilic (water filtering) and hydrophobic (water repellent) forms. In some embodiments, filter element **214** comprises a support layer and an acrylic copolymer membrane formed on the support layer. In some embodiments, the wound dressing **155** according to certain embodiments uses microporous hydrophobic membranes (MHMs). Numerous polymers may be employed to form MHMs. For example, the MHMs may be formed from one or more of PTFE, polypropylene, PVDF and acrylic copolymer. All of these optional polymers can be treated in order to obtain specific surface characteristics that can be both hydrophobic and oleophobic. As such these will repel liquids with low surface tensions such as multi-vitamin infusions, lipids, surfactants, oils and organic solvents.

MHMs block liquids whilst allowing air to flow through the membranes. They are also highly efficient air filters eliminating potentially infectious aerosols and particles. A

single piece of MHM is well known as an option to replace mechanical valves or vents. Incorporation of MHMs can thus reduce product assembly costs improving profits and costs/benefit ratio to a patient.

The filter element **214** may also include an odor absorbent material, for example activated charcoal, carbon fiber cloth or Vitec Carbotec-RT Q2003073 foam, or the like. For example, an odor absorbent material may form a layer of the filter element **214** or may be sandwiched between microporous hydrophobic membranes within the filter element. The filter element **214** thus enables gas to be exhausted through the orifice. Liquid, particulates and pathogens however are contained in the dressing.

The wound dressing **155** may comprise spacer elements **215** in conjunction with the fluidic connector **160** and the filter **214**. With the addition of such spacer elements **215** the fluidic connector **160** and filter **214** may be supported out of direct contact with the absorbent layer **220** or the transmission layer **226**. The absorbent layer **220** may also act as an additional spacer element to keep the filter **214** from contacting the transmission layer **226**. Accordingly, with such a configuration contact of the filter **214** with the transmission layer **226** and wound fluids during use may thus be minimized.

Similar to the embodiments of wound dressings described above, some wound dressings comprise a perforated wound contact layer with silicone adhesive on the skin-contact face and acrylic adhesive on the reverse. Above this bordered layer sits a transmission layer or a 3D spacer fabric pad. Above the transmission layer, sits an absorbent layer. The absorbent layer can include a superabsorbent non-woven (NW) pad. The absorbent layer can over-border the transmission layer by approximately 5 mm at the perimeter. The absorbent layer can have an aperture or through-hole toward one end. The aperture can be about 10 mm in diameter. Over the transmission layer and absorbent layer lies a backing layer. The backing layer can be a high moisture vapor transmission rate (MVTR) film, pattern coated with acrylic adhesive. The high MVTR film and wound contact layer encapsulate the transmission layer and absorbent layer, creating a perimeter border of approximately 20 mm. The backing layer can have a 10 mm aperture that overlies the aperture in the absorbent layer. Above the hole can be bonded a fluidic connector that comprises a liquid-impermeable, gas-permeable semi-permeable membrane (SPM) or filter that overlies the aforementioned apertures.

Wound Dressing with Sensors

A wound dressing that incorporates a number of sensors can be utilized in order to monitor characteristics of a wound as it heals. Collecting data from the wounds that heal well, and from those that do not, can provide useful insights towards identifying measurands to indicate whether a wound is on a healing trajectory.

In some implementations, a number of sensor technologies can be used in wound dressings or one or more components forming part of an overall wound dressing apparatus. For example, as illustrated in FIGS. 2 and 3D, which depict wound dressings **250** and **320** with sensor arrays according to some embodiments, one or more sensors can be incorporated onto or into a wound contact layer, which may be a perforated wound contact layer as shown in FIG. 3D. The wound contact layer in FIGS. 2 and 3D is illustrated as having a square shape, but it will be appreciated that the wound contact layer may have other shapes such as rectangular, circular, oval, etc. In some embodiments, the sensor integrated wound contact layer can be provided as an individual material layer that is placed over

the wound area and then covered by a wound dressing apparatus or components of a wound dressing apparatus, such as gauze, foam or other wound packing material, a superabsorbent layer, a drape, a fully integrated dressing like the Pico or Allevyn Life dressing, etc. In other embodiments, the sensor integrated wound contact layer may be part of a single unit dressing such as described herein.

The sensor-integrated wound contact layer can be placed in contact with the wound and will allow fluid to pass through the contact layer while causing little to no damage to the tissue in the wound. The sensor-integrated wound contact layer can be made of a flexible material such as silicone and can incorporate antimicrobials or other therapeutic agents known in the art. In some embodiments, the sensor-integrated wound contact layer can incorporate adhesives that adhere to wet or dry tissue. In some embodiments, the sensors or sensor array can be incorporated into or encapsulated within other components of the wound dressing such as the absorbent layer or spacer layer described above.

As shown in FIGS. 2 and 3D, five sensors can be used, including, for instance, sensors for temperature (such as, 25 thermistor sensors, in a 5x5 array, ~20 mm pitch), oxygen saturation or SpO2 (such as, 4 or 5 SpO2 sensors, in a single line from the center of the wound contact layer to the edge thereof, 10 mm pitch), tissue color (such as, 10 optical sensors, in 2x5 array, ~20 mm pitch; not all 5 sensors in each row of the array need be aligned), pH (such as, by measuring colour of a pH sensitive pad, optionally using the same optical sensors as for tissue colour), and conductivity (such as, 9 conductivity contacts, in a 3x3 array, ~40 mm pitch). As shown in FIG. 3A, the SpO2 sensors can be arranged in a single line from the center of or near the center of the wound contact layer to the edge of the wound contact layer. The line of SpO2 sensors can allow the sensor to take measurements in the middle of the wound, at the edge or the wound, or on intact skin to measure changes between the various regions. In some embodiments, the wound contact layer or sensor array can be larger than the size of the wound to cover the entire surface area of the wound as well as the surrounding intact skin. The larger size of the wound contact layer and/or sensor array and the multiple sensors can provide more information about the wound area than if the sensor was only placed in the center of the wound or in only one area at a time.

The sensors can be incorporated onto flexible circuit boards formed of flexible polymers including polyimide, polyimide (PI), polyester, polyethylene naphthalate (PEN), polyetherimide (PEI), along with various fluoropolymers (FEP) and copolymers, or any material known in the art. The sensor array can be incorporated into a two-layer flexible circuit. In some embodiments, the circuit board can be a multi-layer flexible circuit board. In some embodiments, these flexible circuits can be incorporated into any layer of the wound dressing. In some embodiments, a flexible circuit can be incorporated into a wound contact layer. For example, the flexible circuit can be incorporated into a wound contact layer similar to the wound contact layer described with reference to FIG. 1B. The wound contact layer can have cutouts or slits that allow for one or more sensors to protrude out of the lower surface of the wound contact layer and contact the wound area directly.

In some embodiments, the sensor-integrated wound contact layer can include a first and second wound contact layer with the flexible circuit board sandwiched between the two layers of wound contact layer material. The first wound contact layer has a lower surface intended to be in contact

with the wound and an upper surface intended to be in contact with flexible circuit board. The second wound contact layer has a lower surface intended to be in contact with the flexible circuit board and an upper surface intended to be in contact with a wound dressing or one or more components forming part of an overall wound dressing apparatus. The upper surface of the first wound contact layer and the lower surface of the second wound contact layer can be adhered together with the flexible circuit board sandwiched between the two layers.

In some embodiments, the one or more sensors of the flexible circuit board can be fully encapsulated or covered by the wound contact layers to prevent contact with moisture or fluid in the wound. In some embodiments, the first wound contact layer can have cutouts or slits that allow for one or more sensors to protrude out of the lower surface and contact the wound area directly. For example, the one or more SpO₂ sensors as shown in FIG. 3D are shown protruding out the bottom surface of the wound contact layer. In some embodiments, the SpO₂ sensors can be mounted directly on a lower surface of the first wound contact layer. Some or all of the sensors and electrical or electronic components may be potted or encapsulated (for example, rendered waterproof or liquid-proof) with a polymer, for example, silicon or epoxy based polymers. The encapsulation with a polymer can prevent ingress of fluid and leaching of chemicals from the components. In some embodiments, the wound contact layer material can seal the components from water ingress and leaching of chemicals.

In some embodiments, gathering and processing information related to the wound can utilize three components, including a sensor array, a control or processing module, and software. These components are described in more detail herein.

FIG. 3A illustrates a flexible sensor array circuit board 300 that includes a sensor array portion 301, a tail portion 302, and a connector pad end portion 303 according to some embodiments. The sensor array portion 301 can include the sensors and associated circuitry. The sensor array circuit board 300 can include a long tail portion 302 extending from the sensor array portion 301. The connector pad end portion 303 can be enabled to connect to a control module or other processing unit to receive the data from the sensor array circuit. The long tail portion 302 can allow the control module to be placed distant from the wound, such as for example in a more convenient location away from the wound.

FIG. 3B illustrates embodiments of the flexible circuit boards with four different sensor array geometries 301A, 301B, 301C, and 301D according to some embodiments. The illustrated embodiments include tail portions 302A, 302B, 302C, and 302D. In some embodiments, four different sensor array geometries shown can be implemented in flexible circuits. While FIG. 3B show four different sensor array formats and configurations, the design 301B and 302B also includes the connector pads end portion 303 configured to provide electrical or electronic connection between the sensor array 301B and a control module. One or more of the designs in 301A, 301C, or 301D can also include a connector pads end portion, such as the portion 303, to allow flexible circuit boards 301A, 301C, or 301D to communicate with a control module or other processing unit. In some embodiments, the sensor array communicates with the control module wirelessly and the tail portion may be omitted.

FIG. 3C shows the sensor array portion 301B of the sensor array design shown of FIG. 3B in more detail. In any one or more of the embodiments of FIG. 2 or 3A-3D, the

sensor array portion can include a plurality of portions that extend either around a perimeter of a wound dressing component such as a wound contact layer, or inward from an outer edge of the wound dressing component. For example, the illustrated embodiments include a plurality of linearly extending portions that may be parallel to edges of a wound dressing component, and in some embodiments, follow the entire perimeter of the wound dressing component. In some embodiments, the sensor array portion may comprise a first plurality of parallel linearly extending portions that are perpendicular to a second plurality of parallel linearly extending portions. These linearly extending portions may also have different lengths and may extend inward to different locations within an interior of a wound dressing component. The sensor array portion preferably does not cover the entire wound dressing component, so that gaps are formed between portions of the sensor array. As shown in FIG. 2, this allows some, and possibly a majority of the wound dressing component to be uncovered by the sensor array. For example, for a perforated wound contact layer as shown in FIGS. 2 and 3D, the sensor array portion 301 may not block a majority of the perforations in the wound contact layer. In some embodiments, the sensor array may also be perforated or shaped to match the perforations in the wound contact layer to minimize the blocking of perforations to fluid flow.

FIG. 3D illustrates a flexible sensor array incorporated into a perforated wound contact layer 320 according to some embodiments. As is illustrated, the sensor array can be sandwiched between two films or wound contact layers. The wound contact layers can have perforations formed as slits or holes as described herein that are small enough to help prevent tissue ingrowth into the wound dressing while allowing wound exudate to flow into the dressing. In some embodiments, the wound contact layers can have one or more slits that increase flexibility of the wound contact layer with integrated sensor array. In some embodiments, one of the wound contact layers can have extra cut outs to accommodate the sensors so that they can contact the skin directly.

Connectivity for the sensor array can vary depending on the various sensors and sensor array designs utilized. In some embodiments, for example as shown in FIG. 3B, a total of 79 connections can be used to connect the components of the sensor array. The sensor arrays can be terminated in two parallel 40-way 0.5 mm pitch Flat Flexible Cable (FFC) contact surfaces, with terminals on the top surface, designed to be connected to an FFC connector such as Molex 54104-4031.

In some embodiments, one or more of thermistors, conductivity sensors, SpO₂ sensors, or color sensors can be used on the sensor array to provide information relating to conditions of the wound. The sensor array and individual sensors can assist a clinician in monitoring the healing of the wound. The one or more sensors can operate individually or in coordination with each other to provide data relating to the wound and wound healing characteristics.

Temperature sensors can use thermocouples or thermistors to measure temperature. The thermistors can be used to measure or track the temperature of the underlying wound or the thermal environment within the wound dressing. The thermometry sensors can be calibrated and the data obtained from the sensors can be processed to provide information about the wound environment. In some embodiments, an ambient sensor measuring ambient air temperature can also be used to assist in eliminating problems associated with environment temperature shifts.

Optical sensors can be used to measure wound appearance using an RGB sensor with an illumination source. In some embodiments, both the RGB sensor and the illumination source would be pressed up against the skin, such that light would penetrate into the tissue and take on the spectral features of the tissue itself.

Light propagation in tissue can be dominated by two major phenomena, scattering and attenuation. For attenuation, as light passes through tissue, its intensity may be lost due to absorption by various components of the tissue. Blue light tends to be attenuated heavily, whilst light at the red end of the spectrum tends to be attenuated least.

Scattering processes can be more complex, and can have various “regimes” which must be considered. The first aspect of scattering is based on the size of the scattering centre compared with the wavelength of incident light. If the scattering center is much smaller than the wavelength of light, then Rayleigh scattering can be assumed. If the scattering center is on the order of the wavelength of light, then a more detailed Mie scattering formulation must be considered. Another factor involved in scattering light is the distance between input and output of the scattering media. If the mean free path of the light (the distance between scattering events) is much larger than the distance traveled, then ballistic photon transport is assumed. In the case of tissue, scattering events are approximately 100 microns apart—so a 1 mm path distance would effectively randomise the photon direction and the system would enter a diffusive regime.

Ultra bright light emitting diodes (LEDs), an RGB sensor, and polyester optical filters can be used as components of the optical sensors to measure through tissue color differentiation. For example, because surface color can be measured from reflected light, a color can be measured from light which has passed through the tissue first for a given geometry. This can include color sensing from diffuse scattered light, from an LED in contact with the skin. In some embodiments, an LED can be used with an RGB sensor nearby to detect the light which has diffused through the tissue. The optical sensors can image with diffuse internal light or surface reflected light.

Additionally, the optical sensors can be used to measure autofluorescence. Autofluorescence is used because the tissue is absorbing light at one wavelength, and emitting at another. Additionally, dead tissue may not auto-fluoresce and so this could be a very strong indication as to if the tissue is healthy or not. Due to blue light (or even UV light) having such a short penetration depth, it may be very useful for example to have a UV light with a red sensitive photodiode nearby (or some other wavelength shifted band) to act as a binary test for healthy tissue, which would auto-fluoresce at a very particular wavelength.

Conductivity sensors can be used to determine the difference between living and dead tissue or to show a change in impedance due to a wound being opened up in morbid tissue. Conductivity sensors can include Ag/AgCl electrodes and an impedance analyser. The conductivity sensors can be used to measure the change of impedance of a region of wound growth by measuring the impedance of the surrounding tissue/area. In some embodiments, the sensor array can utilize conductivity sensors to measure the change in conductivity on perimeter electrodes due to a wound size or wound shape change. In some embodiments, the conductivity sensors can be used in the wound bed or on the perimeter of the wound.

In some embodiments, pH changing pads can be used as a pH sensor. A spectrometer and a broadband white light

source can be used to measure the spectral response of the pH dye. The illumination and imaging can be provided on the surface of the wound dressing that is in contact with the wound and at the same side as the fluid application, the bottom surface. Alternatively, in some embodiments, the illumination and imaging source can be provided on the surface of the wound dressing opposite the bottom surface and away from fluid application or the top surface of the dressing.

In some embodiments, pulse oximetry SpO₂ sensors can be used. To measure how oxygenated the blood is and the pulsatile blood flow can be observed. Pulse oximetry measurements work by taking a time resolved measurement of light absorption/transmission in tissue at two different optical wavelengths. When hemoglobin becomes oxygenated, its absorption spectrum changes with regards to non-oxygenated blood. By taking a measurement at two different wavelengths, one gains a ratio metric measure of how oxygenated the blood is.

The components in the sensor array can be connected through multiple connections. In some embodiments, the thermistors can be arranged in groups of five. Each thermistor is nominally 10 kΩ, and each group of five has a common ground. There are five groups of thermistors, giving a total of 30 connections. In some embodiments, there can be nine conductivity terminals. Each conductivity terminal requires one connection, giving a total of 9 connections. In some embodiments, there can be five SpO₂ sensors. Each SpO₂ sensor requires three connections, plus power and ground (these are covered separately), giving a total of 15 connections. In some embodiments, there can be 10 color sensors. Each color sensor comprises an RGB LED and an RGB photodiode. Each color sensor requires six connections, however five of these are common to every sensor, giving a total of 15 connections. Power and ground are considered separately. In some embodiments, there can be 5 pH sensors. The pH sensors can be a color-change discs, and can be sensed using the color sensors described above. Therefore, the pH sensors require no additional connections. There can be three power rails, and seven ground return signals, giving a total of 10 common connections. In some embodiments, the sensor array can include 25 thermistor (Murata NCP15WB473E03RC), 9 conductivity terminal, 5 SpO₂ (ADPD144RI), 10 RGB LED (such as KPTF-1616RGB-13), 10 RGB Color Sensor, 10 FET, a printed circuit board (PCB), and an assembly.

A control module can be used to interface with the sensor array. In some embodiments, the control module can contain a power source, such as batteries, and electronics to drive the sensors. The control module can also log data at appropriate intervals and allow data transfer to an external computing device, such as a personal computer (PC). The control module can be customized to have various features depending on the sensors used in the sensor array and the data collected by the sensors. In some embodiments, the control module can be comfortable enough and small enough to be worn continuously for several weeks. In some embodiments, the control module can be positioned near the wound dressing or on the wound dressing. In some embodiments, the control module can be positioned in a remote location from the wound dressing and accompanying sensor array. The control module can communicate with the sensor array and wound dressing through electrical wires or through wireless communication whether positioned on the dressing, near the dressing, or remote from the wound dressing. In some embodiments, the control module can be adapted to be

utilized with different sensor arrays and can enable easy replacement of the sensor array.

In some embodiments, the control module can include various requirements and combination of features including but not limited to the features listed in Table 1 below.

TABLE 1

OPTIONAL FEATURES FOR CONTROL MODULE
7 day operation from a single set of batteries
28 day local, non-volatile, storage capacity
Easy to charge, or to replace battery
Wireless link to PC/tablet (such as Bluetooth)
Wired link to PC (optional, micro-USB)
Drive electronics for thermistors
Drive electronics for conductivity sensors
Drive electronics for optical sensors
Drive electronics for SpO2 sensors
Power management
Real Time Clock (RTC) to allow accurate data logging, and correlation with other measurands
Ability to change sample rates and intervals (useful for SpO2) for each sensor
Indication of status via LED, such as (Green: Awake; Flashing green: Charging; Blue: Wireless link established; Flashing blue: Wireless data transfer; Yellow: Wired link established; Flashing yellow: Wired data transfer; Red: Battery low; Flashing red: Battery very low

FIG. 3E illustrates a block diagram 330 of a control module according to some embodiments. The block diagram of the control module includes a conductivity driver box 391 displaying features of the conductivity driver. Box 392 shows the features of the thermistor interface and box 393 shows the features of the optical interface. The control module can include a controller or microprocessor with features similar to those shown in box 394. Real time clock (RTC), Status LEDs, USB connector, Serial Flash, and Debug Connector can be included as features of the control module as shown in FIG. 3E.

In some embodiments, the microprocessor can have one or more of the following features: 2.4 GHz or another suitable frequency radio (either integrated, or external); Supplied Bluetooth software stack; SPI interface; USB (or UART for external USB driver); I2C; 3 channel PWM; 32 GPIO; or 6-channel ADC. In some embodiments, the device can require at least 48 I/O pins or possibly more due to banking limitations. Bluetooth stack typically requires ~20 kB on-board Flash, so a minimum of 32 kB can be required. In some embodiment, 64 kB can be required if complex data processing is considered. The processor core can be ARM Cortex M4 or a similar processor core. In some embodiments, the parts can include ST's STM32L433LC or STM32F302R8, which would require an external radio, or NXP's Kinetis KW range including integrated radio.

In some embodiment, the control module can include a memory component where the amount of local storage depends on the sample rate and resolution of the sensors. For example, an estimated data requirement of 256 Mb (32 MB) can be met by using a serial Flash device from a number of manufacturers (Micron, Spansion).

The control module can utilize one or more analogue switches. In some embodiments, analogue switches with good on resistance and reasonable bandwidth can be used. For example, Analog Devices' ADG72 or NXP's NX3L4051HR can be used. Based on the initial system architecture, 8 of these will be required.

The control module can incorporate a power source, such as a battery. For example, a 300 mWh/day battery can be used. For 7 days this is 2100 mWh. This could be provided

by: a 10 days, non-rechargeable, ER14250 (14.5 mm diameterx25 mm) LiSOC12 cell; or a 7 days, rechargeable, Li 14500 (14.5 mm diameterx500 mm) Li-Ion.

The control module can incorporate a real time clock (RTC). The RTC can be chosen from any RTC devices with crystal. The control module can also include miscellaneous resistors, capacitors, connectors, charge controllers, and other power supplies.

The PCB of the control module can be a 4-layer board, approximately 50 mmx20 mm, or 25 mmx40 mm. The type of PCB used can be largely driven by connection requirements to sensor array.

The enclosure of the control module can be a two-part moulding, with clip features to allow easy access for changing sensor arrays or batteries.

The data collected through the sensor array can be passed through the control module and processed by host software. The software may be executed on a processing device. The processing device can be a PC, tablet, smartphone, or other computer capable of running host software. The processing device executing the software can be in communication with the control module through electrical wires or through wireless communication. In some embodiments, the software may be configured to provide access to the data held on the control module, but not to perform big-data analysis. The host software can include an interface to the control module via Bluetooth or USB. In some embodiments, the host software can read the status of control module, download logged data from control module, upload sample rate control to control module, convert data from control module into format suitable for processing by big-data analysis engine, or upload data to cloud for processing by analysis engine.

The software may be developed for PC (Windows/Linux), tablet or smartphone (Android/iOS), or for multiple platforms.

In some embodiments, a source of negative pressure (such as a pump) and some or all other components of the topical negative pressure system, such as power source(s), sensor(s), connector(s), user interface component(s) (such as button(s), switch(es), speaker(s), screen(s), etc.) and the like, can be integral with the wound dressing. In some embodiments, the components can be integrated below, within, on top of, or adjacent to the backing layer. In some embodiments, the wound dressing can include a second cover layer or a second filter layer for positioning over the layers of the wound dressing and any of the integrated components. The second cover layer can be the upper most layer of the dressing or can be a separate envelope that enclosed the integrated components of the topical negative pressure system.

As used herein the upper layer, top layer, or layer above refers to a layer furthest from the surface of the skin or wound while the dressing is in use and positioned over the wound. Accordingly, the lower surface, lower layer, bottom layer, or layer below refers to the layer that is closest to the surface of the skin or wound while the dressing is in use and positioned over the wound.

Component Positioning

In some embodiments, electrical or electronic components, such as sensors, connections, or the like, can be placed or positioned on or embedded in one or more wound dressing components, which can be placed in or on the wound, skin, or both the wound and the skin. For example, one or more electronic components can be positioned on a wound contact layer side that faces the wound, such as the lower surface 224 of the wound contact layer 222 in FIG. 1B. The wound contact layer can be flexible, elastic, or

stretchable or substantially flexible, elastic, or stretchable in order to conform to or cover the wound. For example, the wound contact layer can be made from a stretchable or substantially stretchable material, such as one or more of polyurethane, thermoplastic polyurethane (TPU), silicone, polycarbonate, polyethylene, polyimide, polyamide, polyester, polyethelene tetraphthalate (PET), polybutalene tetreaphthalate (PBT), polyethylene naphthalate (PEN), polyetherimide (PEI), along with various fluropolymers (FEP) and copolymers, or another suitable material. In some instances, one or more electronic components can be alternatively or additionally placed or positioned on or embedded in any one or more of a transmission layer, absorbent layer, backing layer, or any other suitable layer of the wound dressing.

In some implementations, while it may be desirable for the wound contact layer to be stretchable to better conform to or cover the wound, at least some of the electronic components may not be stretchable or flexible. In such instances, undesirable or excessive localized strain or stress may be exerted on the one or more electronic components, such as on the supporting area or mountings of an electronic component, when the wound is dressed with the wound dressing and the wound contact layer is positioned in or over the wound. For example, such stress can be due to patient movement, changes in the shape or size of the wound (such as, due to its healing), or the like. Such stress may cause movement, dislodgment, or malfunction of the one or more electronic components (for example, creation of an open circuit from a pin or another connector becoming disconnected). Alternatively or additionally, it may be desirable to maintain the position of one or more electronic components, such as one or more sensors, in the same or substantially same location or region on the wound contact layer with respect to the wound (such as, in contact with the wound) so that measurements collected by the one or more electronic components accurately capture changes over time in the same or substantially same location or region of the wound. While the surface of the stretchable wound contact layer may move when, for example, the patient moves, it may be desirable to have the one or more electronic components be located in the same location or region with respect to the wound.

As described herein, in some embodiments, one or more stiff, rigid, or non-stretchable or substantially stiff, rigid, or non-stretchable regions, such as one or more regions of non-stretchable or substantially non-stretchable material, can be mounted, positioned, or placed on the wound contact layer (or another suitable wound dressing component) for supporting one or more electronic components. Mounting, positioning, or placing one or more electronic components in the one or more non-stretchable or substantially non-stretchable regions can prevent formation of localized stress or assist with maintenance of the position of the one or more electronic components with respect to the wound. In some instances, one or more electronic components can be alternatively or additionally flexible, such as mounted or printed on or supported by one or more flexible materials. For example, flexible plastic sheets or substrates, such as polyimide, polyether ether ketone (PEEK), polyester, silicone, or the like, can be used.

FIGS. 4A-4C illustrate a wound dressing 400 with a plurality of electronic components according to some embodiments. As is shown, a sheet or substrate 430 is configured to support one or more electronic components, including an electronic component or module 402 with a plurality of connectors 404 and a plurality of electronic

connections 410, and non-stretchable or substantially non-stretchable regions 422 and 424. The substrate 430 can be a stretchable or substantially stretchable wound contact layer as described herein. The electronic module 402 can be any electronic component described herein, such as a sensor, light source (such as an LED, temperature sensor, optical sensor, etc.), controller or processor (such as a communication processor), or the like. Electronic connections 410 can be tracks printed on the substrate 430, such as using conductive copper, conductive ink (such as silver ink, graphite ink, etc.), or the like. At least some of the electronic connections 410 can be flexible or stretchable or substantially flexible or stretchable. Connectors 404 can be configured to electronically connect the electronic module 402 to the electronic connection 410 (as illustrated in FIG. 4B), which in turn can be connected to other electronic modules (not shown) positioned on the substrate 430, on or in other components of the wound dressing, or external to the wound dressing. Connectors 404 can be pins, leads, bumps, or the like. Additionally or alternatively a socket can be used to support and electronically connect the electronic module 402. Regions 422 and 424 can include non-stretchable or substantially non-stretchable material, such as one or more of suitable adhesive, epoxy, polyester, polyimide, polyamide, PET, PBT, or another type of material with a high Young's modulus. One or more of the regions 422 and 424 can be printed on the substrate 430. As is used herein, printing material on a substrate can include one or more of laminating, adhering, or any other suitable technique.

FIG. 4B illustrates components positioned on the substrate 430. As shown, the electronic module 402 is mounted to or supported by the region 422. A portion or part of the electronic connections 410 is mounted to or supported by the region 424. Also illustrated are slits, holes, or perforations formed in the substrate 430 according to some embodiments. As described herein, the substrate 430 can be perforated using one or more of a cold pin perforation, hot pin perforation, laser ablation perforation, ultrasonic or ultrasound perforation, or the like to make the wound contact layer permeable to liquid and gas. In some implementations, one or more utilized perforation processes can generate a flat or substantially flat substrate around the hole rather than an uneven surface (such as donut-shaped surface). Having a flat or substantially flat substrate can assist in generating a homogenous layer when conformal coating is applied (such as, via spray, brush, or the like as described herein). Further, using a perforation process that leaves the surface of the substrate uneven or substantially uneven can introduce a greater risk of dislodging one or more components, such as the electronic connections 410 or the electronic module 402 when perforations are made around the components.

In certain implementations, perforations are made or patterned around one or more components placed on the substrate 430, such as the electronic connections 410, the electronic module 402, or the regions 422 or 424. As explained herein, component indexing can be used to automatically locate position of the one or more components on the substrate 430 so that the one or more components are not damaged by perforations. In some embodiments, the substrate can be perforated before one or more components illustrated in FIG. 4A as placed on the substrate.

FIG. 4C illustrates optional application of one or more of coating 440 or one or more adhesive regions 452, 454, 456 according to some embodiments. Coating 440 can be conformal coating configured to encapsulate or coat one or more of the substrate 430 or components supported by the substrate, such as the electronic connections 410 or the elec-

tronic module **402**. Coating **440** can provide biocompatibility, shield or protect the electronics from coming into contact with fluids, or the like. Coating **440** can be one or more of a suitable polymer, adhesive, such as 1072-M UV, light, or thermal curable or cured adhesive, Optimax adhesive (such as, NovaChem Optimax 8002-LV), parylene (such as, Parylene C), silicon, epoxy, urethane, acrylated urethane, or another suitable biocompatible and stretchable material. Coating **440** can be thin, such as about 100 microns thick, less than about 100 microns thick, or more than about 100 microns thick. Coating **440** can be applied and cured using one or more of UV, light, or thermal curing. In some implementations, coating **440** can be applied on the other side of the substrate **430** (or side facing away from the wound) particularly if the substrate is not impermeable to fluid. In some embodiments, coating is optional.

One or more adhesive pads, tracks, or regions **452**, **454**, **456** can be applied to the wound facing side of the substrate **430** as illustrated. In some embodiments, first adhesive region **452** can be shaped, sized, or positioned to affix the electronic module **402** in contact with or relative to a first specific or particular part of the wound, such as a first specific or particular area, region, or location in contact with or relative to the wound. Adhesive region **452** can be shaped and sized similarly to the region **422** or the electronic module **402** to affix the module to a particular location in the wound. Similarly, second adhesive region **454** can be shaped, sized, or positioned to affix the portion or part of the electronic connections **410** supported by the region **424** relative to a second specific or particular part of the wound, such as a second specific or particular area, region, or location in contact with or relative to the wound. Another (third) region of adhesive **456** is illustrated which can affix another part of the wound contact layer to another (third) specific or particular part of the wound, such as another (third) specific or particular area, region, or location in contact with or relative to the wound. Adhesive material can be one or more of silicone, such as two-part silicone, one-part silicone, gel, epoxy, acrylic-based material, or another suitable material. Adhesive can be applied and cured using one or more of UV, light, or thermal curing. For example, adhesive can be printed, sprayed, coated, or the like and then cured by UV, light, thermal curing, catalytic, water vapor, or the like. In some embodiments, adhesive is optional.

In some embodiments, one or more adhesive regions can be patterned to position or affix specific components in particular areas, regions, or locations in contact with or relative to the wound even while the substrate **430** is under stress or strain. While the substrate may strain between the adhesive regions, the electronic module **402**, such as a sensor, will remain in the same location in contact with or relative to the wound (due to the adhesive region **452**), thus maintaining the most repeatable signal, and the portion or the part of the electronic connections **410** will remain in the same location in contact with or relative to the wound such that it will not be dragged across the wound (due to the adhesive region **454**) when the substrate **430** undergoes strain. Additionally, the supporting area or mountings of the electronic module **402** will not be put under as much stress because the body (for instance, the skin, which may strain about 20%) will relieve some of the stress (for example, due to the attachment of the wound contact layer to the wound by the one or more adhesive regions) and the substrate will yield around the electronic module. Similar stress relief can be provided to the portion of the electronic connection **410**

which is overlaid by the adhesive region **454**. This can prevent malfunction of the one or more electronic components.

In certain embodiments, pattern of the adhesive regions can be based on the positioning of the one or more electronic components, which can be determined using indexing as described herein. As explained herein, it may be desirable to pattern the adhesive to equalize the stress or strain on the wound contact layer. Adhesive can be patterned to strengthen or support certain areas or regions, such as regions where one or more electronic components are placed, while weakening (or making less rigid) other regions to distribute the stress or to avoid straining the one or more electrical components. For example, it may be desirable to cover at least 50% or more of the wound facing surface of the wound contact layer with the adhesive. In certain implementations, adhesive can be applied to cover or substantially cover the entire wound facing side of the wound contact layer.

In some embodiments, adhesive material used to form the one or more adhesive regions can be non-stretchable or substantially non-stretchable. One or more regions of the non-stretchable or substantially non-stretchable material, such as regions **422** and **424**, may not be used or may be sized or shaped differently from one or more adhesive regions.

Although a single electronic module **402** is illustrated in FIGS. 4A-4C, in certain implementations, a plurality of electronic modules can be used. One or more of the additional electronic modules or one or more electronic connections **410** interconnecting the electronic module **402** and the additional electronic modules can be placed on one or more additional non-stretchable or substantially non-stretchable regions. Additionally or alternatively, adhesive regions can be placed to further affix the one or more electronic modules or electronic connections in contact with or relative to the wound as described herein.

Component Encapsulation and Stress Relief

As described herein, biocompatible coating can be applied to the wound contact layer or electronic components positioned on the wound contact layer. In some embodiments, the wound contact layer includes a thin, flexible substrate that conforms to the wound. For example, the substrate can be made from stretchable or substantially stretchable material or film, such as polyurethane, TPU, silicone, polycarbonate, polyethylene, polyimide, polyamide, polyester, PET, PBT, PEN, PEI, along with various FEP and copolymers, or another suitable material. The substrate may not be biocompatible. Coating can be flexible. Coating can include one or more suitable polymers, adhesives, such as 1072-M adhesive (for example Dymax 1072-M), 1165-M adhesive (such as, NovaChem Optimax 8002-LV, Dymax 1165-M, or the like), 10901-M adhesive (for instance, Dymax 1901-M or 9001-E Dymax), parylene (such as, Parylene C), silicones, epoxies, urethanes, acrylated urethanes, acrylated urethane alternatives (such as, Henkel Loctite 3381), or other suitable biocompatible and substantially stretchable materials. Coating can be thin coating, for example, from about 80 microns or less up to several millimeters or more. As described herein, coating can be applied by laminating, adhering, welding (for instance, ultrasonic welding), curing by one or more of light, UV, heat, or the like. Coating can be transparent or substantially transparent to permit optical detection. Coating can retain bond strength when subjected to sterilization, such as EtO sterilization. Coating can have hardness lower than about A100, A80, A50 or lower. Coating can have elongation at

break higher than about 100%, 200%, 300% or more. Coating can have viscosity of about 8,000-14,500 centipoise (cP). In some cases, coating can have viscosity no less than about 3,000 cP. In some cases, coating can have viscosity less than about 3,000 cP. Coating can be fluorescent.

It may be desirable for a substrate and electronic components supported by the substrate to be conformable as the substrate and the electronic components are intended to be positioned on or in the body. One property of conformability is the extensibility of the coating material as the electronic components may need to be isolated from the wound. Coating applied to the substrate may need to have the ability to stretch with the substrate (in case the substrate is stretchable or substantially stretchable). Pairing the elongation characteristics of both the substrate and coating can maximize the desired properties of the device. In some examples, the substrate can be formed from TPU film. Coating can be formed from acrylated urethane, such as 1165-M Dymax, 1072-M Dymax, or another suitable material as described herein.

The substrate may need to be coated evenly and comprehensively (for example, the substrate may be encapsulated by the biocompatible coating). The substrate (for example, TPU) may be hydrophilic and, accordingly, may need to be encapsulated in hydrophobic coating to create a hydrophobic dressing to be placed on or in the wound.

FIGS. 5A-5B illustrate coating(s) of a wound dressing according to some embodiments. As described herein, one of the sides of a substrate **530** of the wound dressing can include a plurality of electronic components **402** protruding from the surface. This is illustrated, for example, in FIGS. 4A-4C where the electronic module **402** protrudes from the wound facing surface of the substrate **430**. As is shown in FIG. 5A, coating **440A** can be applied to the side of the substrate supporting electronic components. As described herein, coating **440A** can be biocompatible. Coating **440A** can be hydrophobic. Coating **440A** can be substantially stretchable or extensible.

As shown in FIG. 5B, coating **440B** can be applied to the opposite side of the substrate. This can be advantageous when a substrate is not biocompatible or hydrophobic. Coating **440B** can be biocompatible. Coating **440B** can be hydrophobic. Coating **440B** can be substantially stretchable or extensible. Coatings **440A** and **440B** can be the same or different. The substrate **530** can be encapsulated in the coating as shown in FIG. 5B. Although not illustrated, the left and right sides of the substrate **530** are also encapsulated in the coating.

FIG. 6 illustrates coating a wound dressing with two biocompatible coatings according to some embodiments. Electronic components **402** supported by the substrate **530** can be coated with coating **640A**, particularly if the substrate **530** is stretchable or substantially stretchable. As described herein, coating **640A** can be non-stretchable or substantially non-stretchable to provide stress relief for the electronic components (which may include electronic modules or electronic connections). Coating **640A** can be applied on and around the electronic components. Coating **640A** can be biocompatible. Coating **640A** can be hydrophobic.

Non-stretchable or substantially non-stretchable coating described herein, such as the coating **640A**, can be formed from acrylated or modified urethane material (such as, Henkel Loctite 3211). For example, coating can be one or more of Dymax 1901-M, Dymax 9001-E, Dymax 20351, Dymax 20558, Henkel Loctite 3211, or another suitable material. Coating can have viscosity from about 13,500 cP to 50,000 cP before being cured or from about 3,600 cP to

about 6,600 cP before being cured. In some cases, coating can have viscosity of no more than about 50,000 cP. Coating can have hardness from about D40 to about D65 and/or linear shrinkage of about 1.5-2.5%. Coating can be transparent or substantially transparent to permit optical detection. Coating may be colorless or substantially colorless. Coating **640A** can be fluorescent. Coating can retain bond strength when subjected to sterilization, such as EtO sterilization.

As illustrated, coating **640B** can be applied to the remaining surface of the side of the substrate supporting the electronic components. Coating **640B** can also be applied to the opposite side of the substrate. Although not illustrated, the left and right sides of the substrate **530** are also encapsulated in the coating. Coating **640B** can be biocompatible. Coating **640B** can be hydrophobic. Coating **640B** can be substantially stretchable or extensible. Coating **640B** may be similar to any of the one or more flexible or substantially flexible coatings described herein. For example, coating **640B** may be formed from acrylated urethane or its alternative, such as 1165-M Dymax, 1072-M Dymax, Henkel Loctite 3381 or another suitable material.

In some embodiments, non-stretchable or substantially non-stretchable coating may not be biocompatible. As illustrated in FIG. 7, the electronic components **402** supported by the substrate **530** are coated with non-stretchable or substantially non-stretchable coating **740A**, which is not biocompatible. A second coating **740B** can be applied to the side of the substrate **530** supporting the electronic components. Coating **740B** can be applied over coating **740A**. Coating **740B** can also be applied to the opposite side of the substrate. Although not illustrated, the left and right sides of the substrate **530** are also encapsulated in coating **740B**. Coating **740B** can be biocompatible. Coating **740B** can be hydrophobic. Coating **740B** can be substantially stretchable or extensible.

Coating a thin, flexible substrate with biocompatible material is not trivial because the substrate may need to be coated on the side where electronic components are positioned and on the opposite side. In addition, the substrate may need to be coated evenly and comprehensively (for example, the substrate may be encapsulated by the biocompatible coating).

In some embodiments, a device **500** for coating a wound contact layer as shown in FIG. 8 can be used. The device **500** includes a bottom frame **514** and a top frame **512** attached to the frame **514**. Substrate **530** is held in tension or substantially in tension between the frames **514** and **512**. In some implementations, the substrate **530** can be mounted on a backing, such as a substantially rigid backing made of material with high a Young's modulus (for instance, PET, PBT, or another suitable material). The backing can be shaped as a frame and can be attached to the periphery of the substrate **530**. The substrate **530** is clamped or held in the device **500** so that the substrate does not sag. In some implementations, the frame **514** can be mounted on a base as described herein.

In some embodiments, coating can be applied thinly and evenly. For example, coating can be sprayed. In some embodiments, biocompatible coating can be applied to the wound contact layer by a device **600** of FIG. 9. As is illustrated, the substrate **530** is held by the device **500**. Coating is applied by the device **610**, which can spray the coating material on both sides of the substrate **530**. For example, after a first side of the substrate **530** has been coated, the device **500** can be flipped to coat the opposite side of the substrate **530**. The frames **514** and **512** can be

made from material to which coating does not stick. Such material can include one or more of PTFE, nylon, or another suitable material. For example, PTFE frames are illustrated in the figures.

As described herein, one of the sides of the wound contact layer can include a plurality of electronic components protruding from the surface. This is illustrated, for example, in FIGS. 4A-4C where the electronic module **402** protrudes from the wound facing surface of the substrate **430**. To efficiently and accurately coat the opposite side of such substrate, a plate or mold **700** of FIG. **10** can be used in some embodiments. As is illustrated, the mold **700** has recesses **710** into which one or more electronic components can be positioned. Such recesses can also be referred to as indentations, notches, engravings, wells, or contours. In some embodiments, the recesses **710** are shaped to allow the electronic components to be comfortably positioned. The opening area or depth of the recesses **710** can be larger than the combined area or depth of the electronic components and the coating to provide comfortable support. Positioning the one or more electronic components into one or more recesses permits the opposite side of the substrate to be held flat or substantially flat or smooth so that coating can be evenly applied to that side. In addition, the mold **700** can prevent the substrate from sagging.

In certain implementations, the mold **700** can be made from material to which coating does not stick. Such material can include one or more of PTFE, nylon, or another suitable material. For example, a PTFE mold is illustrated in the figures.

In some embodiments, a mold can include recesses **710** shaped or arranged to permit coating of various substrates that may have different arrangements of electronic components. The mold **700** can include redundant or additional recesses **710** that are not in use when, for example, a first substrate is being coated. At least some of such additional recesses **710** can be used when a second substrate is being coated because they are arranged or shaped to permit positioning of the electronic components of the second substrate.

FIGS. **11** and **12A-12B** illustrate a device **800** for coating a wound dressing according to some embodiments. In the device **800**, the mold **700** is positioned on a base **518**, which provides support. The base **518** can be made from material to which coating does not stick. Such material can include one or more of nylon, PTFE, or another suitable material. For example, a nylon base is illustrated in the figures.

The frame **514** is also positioned on the base as illustrated. In some embodiments, the frame **514** includes one or more pins that are configured to attach to one or more holes on the base. The pins can be dowel pins.

The frame **512** can also be attached to the frame **514** as illustrated. In certain implementations, the attachment is performed using one or more pins positioned on one of the frames and matching holes positioned on the other frame. The pins can be dowel pins.

In the illustrated arrangement, a substrate (not shown) can be positioned with the side supporting the electronic components placed on the mold **700** and be held in tension between the frames **514** and **512**. This can permit applying the coating to the side opposite that which supports the electronic components. Subsequently, the mold **700** can be removed, the substrate can be flipped and positioned between the frames **514** and **512** as described herein so that the side supporting the electronic components can be coated.

In some embodiments, a side of the substrate supporting the electronic components is coated first. The device **500** (without the mold) or **800** (with the mold) can be used hold

the substrate between the frames **514** and **512**. The mold **700** can have thickness that takes into account thickness of the coating. The mold **700** can have thickness of the frame **514** minus the thickness of the coating. For example, the frame **514** can be 10 mm thick and the mold **700** can be 9.85 mm thick when 150 micron (0.15 mm) coating is applied to a side of the substrate supporting the electronic components. When the substrate is flipped and the coated side supporting the electronic components is positioned on the mold **700**, the substrate is precisely leveled on the mold **700** to be held in tension between the frames **514** and **512** to allow coating of the opposite (non-component) side of the substrate.

In some implementations, rigid or substantially rigid release layer or liner **1010** as illustrated in FIG. **13** can be additionally or alternatively used. Release liner **1010** can be applied to the substrate **530** to keep the substrate in tension or substantially in tension so that the substrate can be coated. Release liner **1010** can be applied to a first side of the substrate **530** (for example, the side not supporting the electronic components), permitting the opposite side to be coated. Afterwards, release liner **1010** can be removed and the other side (for example, the side supporting the electronics) can be coated. Release liner **1010** may be applied to the coated side to permit coating of the other side. Release liner can be shaped as a window frame as illustrated in FIG. **13**. Release liner can be adhered to the substrate or attached by any other suitable method.

In certain implementations, release liner **1010** can serve as the backing described herein.

In some embodiments, as illustrated in FIGS. **14A-14B**, a mold of the wound contact layer can be cast to enable the wound contact layer to be held flat or substantially flat during coating. As shown in FIG. **14A**, casting material **1110** can be poured to cast a form or mold **1120**. The mold includes recesses **1122** sized, shaped, and arranged to match the plurality of electronic components supported by a wound contact layer. Such recesses can also be referred to as indentations, notches, engravings, wells, or contours.

FIG. **14B** illustrates coating the substrate **530** using the mold **1120**. The substrate **530** includes a plurality of electronic components **1102** protruding from the surface of the substrate. The electronic components **1102** are positioned in the recesses **1122** of the mold **1120** so that the opposite side of the substrate is substantially flat. Coating **1140** is evenly applied to encapsulate the opposite side of the substrate and its sides.

The side of the substrate **530** supporting the components can be coated before or after coating of the opposite side. For example, a release liner, such as the liner **1010**, or another backing can be applied to the opposite, uncoated side to coat the side of the substrate **530** supporting the electronic components. Afterwards, the substrate **530** can be flipped and placed in the mold **1120** to coat the opposite side as illustrated in FIG. **14B**. As described herein, the recesses **1122** of the mold **1120** can be shaped and sized to account for the coating on the electronic components.

As described herein, in some embodiments, acrylated urethanes can be used as coating material as these polymers have suitable adhesive properties and extensibility. Spray coating acrylated urethanes using the compressed air or inert gas can lead to oxygen inhibition of the polymerization reaction to cure the acrylated urethanes. Removal of oxygen from the system leads to removal of its negative effect on the polymerization reaction to cure the acrylated urethanes.

FIG. **15** illustrates spray coating a wound dressing according to some embodiments. The spray device **1200** includes a dispenser **1230** connected to a pressurized cylinder **1220**

storing air or inert gas. Force of compressed air or gas causes coating **1240** to be sprayed from the dispenser **1230** onto the substrate **530**. The substrate can be held in tension or substantially in tension by device **1210**, which can include at least one of a plurality of frames or a mold as described herein. Coating **1240** can be biocompatible. Coating **1240** can be hydrophobic. Coating **1240** can be substantially stretchable or extensible.

In some embodiments, non-stretchable or substantially non-stretchable coating can be applied to at least some of the plurality of electronic components. FIG. **16** illustrates applying non-stretchable material to a wound dressing according to some embodiments. The spray device **1000** includes a dispenser **1030** connected to a pressurized cylinder **1020** storing air or inert gas. Force of compressed air or gas causes coating **1110** to be sprayed from the dispenser **1030** onto a connecting track **410**. Coating **1110** can be stretchable or substantially non-stretchable. Alternatively or additionally to coating the track **410**, an electronic module can also be coated.

In some embodiments, a single layer of stretchable or non-stretchable coating can be applied. In some embodiments, multiple layers of stretchable or non-stretchable coating can be applied. For example, multiple layers of non-stretchable coating can be applied to achieve desired stiffness or rigidity.

FIGS. **17A-17B** illustrate comparisons of performance without and with non-stretchable material according to some embodiments. FIG. **17A** illustrates how much an electrical connection that has not been coated with non-stretchable or substantially non-stretchable coating stretches. Stretching may be caused, for example, by movement of the patient.

FIG. **17B** illustrates how much an electronic connection that has been coated with non-stretchable or substantially non-stretchable coating stretches. As is illustrated, both uncoated and coated electronic connections **410A** and **410C** are about the same length when not stretched. However, uncoated electronic connection **410B** stretches to a much greater length than the coated electronic connection **410D**.

In some embodiments, wound dressings described herein may need to comply with one or more safety standards, such as IEC 60601 standard for the safety and effectiveness of medical electrical equipment. Such one or more standards can require highly rigorous test method(s) to ensure the electrical safety of the wound dressing. Coatings described herein, such as coatings **440**, **440A**, **440B**, **640A**, **640B**, **740A**, **740B**, **1240** can be applied to the substrate to ensure compliance with the applicable safety standard(s). For example, coatings can protect the electrical components of the wound dressing against liquid ingress, ensure electrical safety, or the like. Coatings described herein can be formed from material(s) that comply with the one or more applicable safety standards.

In some embodiments, coating can include one or more pre-existing materials, such as film. Such pre-existing materials can be manufactured or tested to comply with the one or more applicable safety standards, such as IEC 60601 standard, before applying the one or more materials to the substrate as described herein. In certain implementations, pre-existing material can be TPU, acrylated urethane, or another material.

In some implementations, coating can be applied over the electronic components, which may cause the coating layer to experience localized thinning or stretching. This may be due to uneven surface of the substrate as a result of placement of

the electronic components. In some cases, localized thinning or stretching may be present or be detectable when the coating is not sprayed.

In certain embodiments, electromagnetic/radiofrequency shielding can be applied to the coated surface to protect the electronic components from electromagnetic interference. For example, conductive ink can be used. The ink can be silicone, silver, or the like.

Component Encapsulation and Stress Relief with a Perforated Substrate

In some embodiments, the substrate **430** can include one or more perforations. Such one or more perforations can improve one or more of the accuracy, efficiency, or speed of the coating process as described below. The one or more perforations can be made in the substrate **430** to improve the coating process.

FIG. **18** illustrates a wound dressing **1800** with one or more perforations according to some embodiments. The illustrated dressing **1800** includes a substrate **430** supporting one or more electronic modules **402** electrically connected by one or more connectors **404** to one or more electronic connections **410**. The electric connection(s) between a module **402** and one or more electronic connections **410** can be made by soldering **412** the one or more connectors **404** of the module **402** to the one or more electronic connections **410** or by other suitable means, such as using a socket, surface mounting, or the like. The substrate **430** includes one or more perforations **470**. As illustrated, a perforation **470** can be positioned under the module **402**. In some implementations, additional perforations can be made under the module **402**. In some cases, one or more perforations can be made not under or away from the module **402**.

Any of the one or more perforations **470** can provide escape for gas or air bubbles that may form when coating the substrate **430** and one or more components supported by the substrate. As described herein, removal of oxygen or air can lead to removal of its negative effect on the polymerization reaction to cure acrylated urethanes. FIG. **19A** illustrates coating **1300A** of the wound dressing **1800** according to one or more embodiments. As described herein (for example, with reference to FIGS. **6-7**), the one or more modules **402** (and one or more electronic connections **410**) can be coated with non-stretchable or substantially non-stretchable coating to provide stress relief. FIG. **19A** illustrates such coating **480** being applied. The coating **480** can flow under the module **402** as illustrated. This can result in any gas or air escaping through any of the one or more perforations **470** instead of the gas or air being trapped within the coating or under the module **402**. In some cases, coating **480** has sufficient viscosity to facilitate efficient flow, while not being too viscous to not provide the necessary stress relief for the module **402** as material with higher viscosity may not fully conform around the module **402**. As described herein, coating **480** can have viscosity of about 13,500-50,000 cP or about 3,600-6,600 cP (for example, about 17,000 cP). In some cases, coating can have viscosity of no more than about 50,000 cP. As illustrated, any of the one or more perforations **470** can be completely or partially filled with the coating **480**. In some implementations, the coating process can be sped up by the generation of a pressure difference across the substrate **430**. For example, applying higher pressure on the top side of the substrate **430** (component side as shown) than on the bottom, opposite side of the substrate **430** can force the coating **480** to flow through the perforation **470**. In some implementations, higher pres-

sure can be applied by spray coating the top side of the substrate **430**, such as spray coating with compressed air or inert gas.

FIG. **19B** illustrates coating **1300b** of a wound dressing **1800** according to some embodiments. The wound dressing **1200** can already be coated with coating **480** as described in connection with FIG. **19A**. As described herein, additional coating(s) can be applied to the wound dressing **1200**. For example, as described with reference to FIGS. **5A-5B**, such additional coating(s) can be one or more of biocompatible, hydrophobic, or substantially stretchable or extensible. The additional coating(s) can be used to encapsulate or substantially encapsulate the substrate **430**.

As illustrated in FIG. **19B**, one or more of additional coatings **492** and **494** can be applied to the wound dressing **1200** on the bottom side of the substrate **430**. Coating **492** can be applied to the top side (or component side) of the substrate **430**. Coating **494** can be applied to the opposite, bottom side of the substrate **430**.

In some embodiments, one or more release liners may be used during the process of making or coating the wound dressing **1200**. For example, there can be a release liner (not shown) on the bottom side of the substrate **430**, which can be peeled off following the successful application of coating **492** and before coating **494** is applied. There can be an additional liner applied to the top side of the substrate **430** prior to soft coat **494** being applied, which may be removed thereafter. Using one or more of such release liners can ensure that coating **492** is not applied to the areas where coating **494** should be applied and vice versa.

Any one or more of the coatings **480**, **492**, or **494** can be applied using any one or more of the approaches described herein. In some cases, any of the one or more perforations **470** can be completely or partially filled with one or more coatings described herein, such as one or more coatings **480** or **494**. In some implementations, any of the one or more perforations can be partially filled with one or more coatings and can allow fluid, such as wound exudate, to pass through the wound dressing.

Other Variations

In some embodiments, one or more electronic components can be positioned on the side of a wound contact layer opposite the side that faces the wound. Systems and methods described herein are equally applicable to such wound contact layers. Although spraying the coating is described above, other suitable methods for applying the coating can be used in certain embodiments. Such methods can include one or more of dip coating, spin coating, vapor deposition, chemical deposition, electrochemical deposition, roll-to-roll coating, laminating, adhering, welding (for instance, ultrasonic welding), curing by one or more of light, UV, heat, or the like.

Although certain embodiments described herein relate to wound dressings, systems and methods disclosed herein are not limited to wound dressings or medical applications. Systems and methods disclosed herein are generally applicable to electronic devices in general, such as electronic devices that can be worn by or applied to a user.

Any value of a threshold, limit, duration, etc. provided herein is not intended to be absolute and, thereby, can be approximate. In addition, any threshold, limit, duration, etc. provided herein can be fixed or varied either automatically or by a user. Furthermore, as is used herein relative terminology such as exceeds, greater than, less than, etc. in relation to a reference value is intended to also encompass being equal to the reference value. For example, exceeding a reference value that is positive can encompass being equal to or greater than the reference value. In addition, as is used

herein relative terminology such as exceeds, greater than, less than, etc. in relation to a reference value is intended to also encompass an inverse of the disclosed relationship, such as below, less than, greater than, etc. in relations to the reference value. Moreover, although blocks of the various processes may be described in terms of determining whether a value meets or does not meet a particular threshold, the blocks can be similarly understood, for example, in terms of a value (i) being below or above a threshold or (ii) satisfying or not satisfying a threshold.

Features, materials, characteristics, or groups described in conjunction with a particular aspect, embodiment, or example are to be understood to be applicable to any other aspect, embodiment or example described herein unless incompatible therewith. All of the features disclosed in this specification (including any accompanying claims, abstract and drawings), or all of the steps of any method or process so disclosed, may be combined in any combination, except combinations where at least some of such features or steps are mutually exclusive. The protection is not restricted to the details of any foregoing embodiments. The protection extends to any novel one, or any novel combination, of the features disclosed in this specification (including any accompanying claims, abstract and drawings), or to any novel one, or any novel combination, of the steps of any method or process so disclosed.

While certain embodiments have been described, these embodiments have been presented by way of example only, and are not intended to limit the scope of protection. Indeed, the novel methods and systems described herein may be embodied in a variety of other forms. Furthermore, various omissions, substitutions and changes in the form of the methods and systems described herein may be made. Those skilled in the art will appreciate that in some embodiments, the actual steps taken in the processes illustrated or disclosed may differ from those shown in the figures. Depending on the embodiment, certain of the steps described above may be removed, others may be added. For example, the actual steps or order of steps taken in the disclosed processes may differ from those shown in the figure. Depending on the embodiment, certain of the steps described above may be removed, others may be added. For instance, the various components illustrated in the figures may be implemented as software or firmware on a processor, controller, ASIC, FPGA, or dedicated hardware. Hardware components, such as controllers, processors, ASICs, FPGAs, and the like, can include logic circuitry. Furthermore, the features and attributes of the specific embodiments disclosed above may be combined in different ways to form additional embodiments, all of which fall within the scope of the present disclosure.

Although the present disclosure includes certain embodiments, examples and applications, it will be understood by those skilled in the art that the present disclosure extends beyond the specifically disclosed embodiments to other alternative embodiments or uses and obvious modifications and equivalents thereof, including embodiments which do not provide all of the features and advantages set forth herein. Accordingly, the scope of the present disclosure is not intended to be limited by the specific disclosures of preferred embodiments herein, and may be defined by claims as presented herein or as presented in the future.

Conditional language, such as “can,” “could,” “might,” or “may,” unless specifically stated otherwise, or otherwise understood within the context as used, is generally intended to convey that certain embodiments include, while other embodiments do not include, certain features, elements, or steps. Thus, such conditional language is not generally

intended to imply that features, elements, or steps are in any way required for one or more embodiments or that one or more embodiments necessarily include logic for deciding, with or without user input or prompting, whether these features, elements, or steps are included or are to be performed in any particular embodiment. The terms “comprising,” “including,” “having,” and the like are synonymous and are used inclusively, in an open-ended fashion, and do not exclude additional elements, features, acts, operations, and so forth. Also, the term “or” is used in its inclusive sense (and not in its exclusive sense) so that when used, for example, to connect a list of elements, the term “or” means one, some, or all of the elements in the list. Further, the term “each,” as used herein, in addition to having its ordinary meaning, can mean any subset of a set of elements to which the term “each” is applied.

Conjunctive language such as the phrase “at least one of X, Y, and Z,” unless specifically stated otherwise, is otherwise understood with the context as used in general to convey that an item, term, etc. may be either X, Y, or Z. Thus, such conjunctive language is not generally intended to imply that certain embodiments require the presence of at least one of X, at least one of Y, and at least one of Z.

Language of degree used herein, such as the terms “approximately,” “about,” “generally,” and “substantially” as used herein represent a value, amount, or characteristic close to the stated value, amount, or characteristic that still performs a desired function or achieves a desired result. For example, the terms “approximately,” “about,” “generally,” and “substantially” may refer to an amount that is within less than 10% of, within less than 5% of, within less than 1% of, within less than 0.1% of, and within less than 0.01% of the stated amount. As another example, in certain embodiments, the terms “generally parallel” and “substantially parallel” refer to a value, amount, or characteristic that departs from exactly parallel by less than or equal to 15 degrees, 10 degrees, 5 degrees, 3 degrees, 1 degree, or 0.1 degree.

The scope of the present disclosure is not intended to be limited by the specific disclosures of preferred embodiments in this section or elsewhere in this specification, and may be defined by claims as presented in this section or elsewhere in this specification or as presented in the future. The language of the claims is to be interpreted broadly based on the language employed in the claims and not limited to the examples described in the present specification or during the prosecution of the application, which examples are to be construed as non-exclusive.

What is claimed is:

1. A method for coating a wound dressing, the method comprising:

coating a plurality of electronic components supported by a first wound-facing side of a flexible substrate of the wound dressing with a first coating;

coating the first side of the flexible substrate including the plurality of electrical components and a second side of the flexible substrate opposite the first side with a second coating; and

making at least one perforation extending between the first side and the second side of the flexible substrate.

2. The method of claim 1, wherein the first coating is non-stretchable.

3. The method of claim 1, wherein the second coating is stretchable.

4. The method of claim 1, wherein the second coating is more stretchable than the first coating.

5. The method of claim 1, wherein the second coating is biocompatible.

6. The method of claim 1, wherein the second coating is hydrophobic.

7. The method of claim 1, wherein the second coating is formed from material compliant with IEC 60601 standard.

8. The method of claim 1, wherein coating the first side of the flexible substrate with the second coating comprises coating the first coating covering the plurality of electronic components.

9. The method of claim 1, wherein coating the first side of the flexible substrate with the second coating comprises spraying the second coating.

10. The method of claim 9, wherein the spraying comprises spraying with compressed air or inert gas.

11. The method of claim 1, wherein the first coating comprises at least one of Dymax 1901-M, Dymax 9001-E, Dymax 20351, Dymax 20558, or Henkel Loctite 3211.

12. The method of claim 1, wherein the first coating has viscosity from about 13,500 cP to 50,000 cP before being cured or from about 3,600 cP to about 6,600 cP before being cured.

13. The method of claim 1, wherein the second coating comprises at least one of 1165-M Dymax, 1072-M Dymax, or Henkel Loctite 3381.

14. The method of claim 1, wherein the flexible substrate is a wound contact layer.

15. A method for coating a wound dressing, the method comprising:

coating a plurality of electronic components supported by a first wound-facing side of a flexible substrate of the wound dressing with a first coating;

coating the first side of the flexible substrate including the plurality of electrical components and a second side of the flexible substrate opposite the first side with a second coating,

wherein the second coating is more stretchable than the first coating, and wherein at least one of the first coating or the second coating at least partially fills at least one perforation through the substrate.

16. A wound dressing comprising:

a flexible substrate with a first wound-facing side, a second side opposite the first side, and a thickness between the first and second sides;

a plurality of electronic components supported by the first side of the flexible substrate;

a first coating covering the plurality of electronic components;

a second coating covering the first side of the flexible substrate including the plurality of electrical components and the second side of the flexible substrate; and one or more perforations extending through the entire thickness of the flexible substrate.

17. The wound dressing of claim 16, wherein the first coating is non-stretchable and the second coating is stretchable.

18. The wound dressing of claim 16, wherein the second coating is more stretchable than the first coating.

19. The wound dressing of claim 16, wherein the second coating covers the first coating covering the plurality of electric components.

20. The wound dressing of claim 16, wherein the flexible substrate comprises thermoplastic polyurethane.

21. The method of claim 1, wherein the at least one perforation also extends through at least one of the first coating or the second coating.